

US3862128 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:06:48

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US3862128

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

[Participant ID](#)

US3862128

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

US3862128

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:46:46

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Date of Informed Consent (dd MMM yyyy)	4 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:46:46

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	SUPERFICIAL LEG BLOOD CLOT
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	MYALGIA AS SIDE EFFECT OF LETROZOLE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	LEFT BREAST CANCER(INVASIVE DUCTAL CARCINOMA)
Start date (dd MMM yyyy)	UN MAY 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2018
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	HASHIMOTO'S HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	ARTHALGIAS AS SIDE EFFECT OF LETROZOLE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	ALTITUDE SICKNESS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Condition	ALLERGY TO ANESTHESIA MEDICATION(TRANSAMINITIS)
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 09:51
Height (xxx.x)	166.3 cm
Weight (xxx.x)	169 lb
BMI (xxx.x)	27.77663 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Date of assessment (dd MMM yyyy) 4 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1999

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

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

HEALTH ADMINISTRATION

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:46:46

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 189693

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m²) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

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)	4 SEP 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 09:51
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	068 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	088 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

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)	4 SEP 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 12:10
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	064 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	020 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	091 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 11:37 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 11:37

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	4 SEP 2020

Collection time (00:00-23:59)	10:38 (24 HR)

Collection date and time (derived)	4 SEP 2020 10:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:15	4 SEP 2020 10:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:06

PC Open Date & Time

04 SEP 2020 11:57

PC Close Date & Time

04 SEP 2020 14:27

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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	04 SEP 2020 19:35
PC Open Date & Time	04 SEP 2020 15:22
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

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

05 SEP 2020 21:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

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

06 SEP 2020 20:09

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

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

97.3 °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

07 SEP 2020 17:58

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 22:21

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 18:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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

10 SEP 2020 17:44

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 11:59

PC Open Date & Time

04 SEP 2020 11:57

PC Close Date & Time

04 SEP 2020 14:27

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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 ☐

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

3

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)**

15

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

04 SEP 2020 19:34

PC Open Date & Time

04 SEP 2020 15:22

PC Close Date & Time

05 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

3

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)**

15

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 21:19

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 20:09

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 17:58

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 22:22

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 18:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 17:43

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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 ☐

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 11:58
PC Open Date & Time	04 SEP 2020 11:57
PC Close Date & Time	04 SEP 2020 14:27

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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 ☐

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 19:31
PC Open Date & Time	04 SEP 2020 15:22
PC Close Date & Time	05 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

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 ☒

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	05 SEP 2020 21:18
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

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 ☒

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EAB) (1725)

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	06 SEP 2020 20:09
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	08 SEP 2020 22:22
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	09 SEP 2020 18:52
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	10 SEP 2020 17:43
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3862128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862128

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:46:30

Generated On: 10 Jun 2021 10:06:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862128

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:46:30

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:46:30

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:46:30

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 10:26
Temperature (xxx.x)	098.0 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	069 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	089 mmHg
Diastolic Blood Pressure units	MMHG

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 13:15
Temperature (xxx.x)	097.9 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	076 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	020 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	087 mmHg
Diastolic Blood Pressure units	MMHG

US3862128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

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 OCT 2020

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 02 OCT 2020 12:45

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

What was the frequency of the study treatment dosing? ONCE

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

US3862128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 2 OCT 2020

Collection time (00:00-23:59) 11:30 (24 HR)

Collection date and time (derived) 2 OCT 2020 11:30

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	11:09	2 OCT 2020 11:09

US3862128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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

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

02 OCT 2020 13:17

PC Open Date & Time

02 OCT 2020 13:05

PC Close Date & Time

02 OCT 2020 15:35

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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 98.2 °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	02 OCT 2020 20:04
PC Open Date & Time	02 OCT 2020 16:30
PC Close Date & Time	03 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

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	99.0 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	03 OCT 2020 18:32
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 04 OCT 2020 20:36

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

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

97.2 °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

05 OCT 2020 22:17

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 20:15

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

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.

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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

97.7 °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

07 OCT 2020 21:04

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp 08 OCT 2020 22:16

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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

1

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

02 OCT 2020 13:15

PC Open Date & Time

02 OCT 2020 13:05

PC Close Date & Time

02 OCT 2020 15:35

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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 ☐

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

3

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)**

18

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

02 OCT 2020 20:08

PC Open Date & Time

02 OCT 2020 16:30

PC Close Date & Time

03 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

28

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)**

40

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 18:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

75

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)**

34

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 18:45

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

60

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 22:19

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

52

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 20:03

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

45

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 21:05

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

45

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 - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 22:15

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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 ☐

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 13:16
PC Open Date & Time	02 OCT 2020 13:05
PC Close Date & Time	02 OCT 2020 15:35

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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 ☐

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 20:09
PC Open Date & Time	02 OCT 2020 16:30
PC Close Date & Time	03 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	03 OCT 2020 18:33
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	04 OCT 2020 18:46
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	05 OCT 2020 22:17
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	06 OCT 2020 20:04
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	07 OCT 2020 21:03
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

Yes ☐	
PC Time stamp	08 OCT 2020 22:15
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

35

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

PC Time Stamp 09 OCT 2020 21:41

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 9

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

30

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

PC Time Stamp 10 OCT 2020 22:10

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 10

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☒

PC Time Stamp

11 OCT 2020 12:01

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 OCT 2020 21:42
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 OCT 2020 22:10
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 OCT 2020 12:01
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3862128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:46:30

Generated On: 10 Jun 2021 10:06:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3862128

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:46:30

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:46:30

Generated On: 10 Jun 2021 10:06:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3862128

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:46:30

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

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

NO ATTEMPT MADE

If Contact Not Made, please provide Comments

US3862128

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID VISIT3

US3862128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:46:46

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 07:20:20
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 14:41:33

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

29 NOV 2020 12:06:57

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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	06 DEC 2020 09:17:00
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 10:23:41

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

Date and time of submission

22 DEC 2020 12:43:38

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

Date and time of submission

29 DEC 2020 13:43:03

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

Date and time of submission

03 JAN 2021 07:19:09

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 07:39:02

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 08:19:52

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 09:47:15

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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	01 FEB 2021 07:20:40
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

07 FEB 2021 08:22:48

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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	14 FEB 2021 07:30:10
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 00:15:31
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

Date and time of submission

14 MAR 2021 08:06:02

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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	21 MAR 2021 07:29:25
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

28 MAR 2021 07:13:43

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

04 APR 2021 08:01:47

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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 07:27:35

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

20 APR 2021 07:24:47

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

25 APR 2021 06:41:41

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	02 MAY 2021 07:41:33
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

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17 JUN 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 MAR 2022 00:01

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10 MAR 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 MAR 2022 00:01

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17 MAR 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JUN 2022 00:01

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16 JUN 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JUL 2022 00:01

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14 JUL 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 AUG 2022 00:01

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18 AUG 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3862128

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:06:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 00:15:46

US3862128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:30:42

Generated On: 10 Jun 2021 10:06:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862128

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:30:42

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3862128

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3862128

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	31 MAR 2021

Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒

Folder OID	VISIT4

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

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) _____

US3862128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

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.

US3862128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 31 MAR 2021

Collection time (00:00-23:59) 14:04 (24 HR)

Collection date and time (derived) 31 MAR 2021 14:04

US3862128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:54:14

Generated On: 10 Jun 2021 10:06:48

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3862128

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:54:14

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862128

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 14:25:06

Generated On: 10 Jun 2021 10:06:48

Date of Contact	2 NOV 2020
Time of Contact	09:30
Date and Time of Contact (derived)	2 NOV 2020 09:30
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 ☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	19 OCT 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 ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 OCT 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	21 OCT 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 ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 OCT 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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 OCT 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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 OCT 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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	25 OCT 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 ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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 ☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 OCT 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	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	27 OCT 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 ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	28 OCT 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 ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	29 OCT 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	30 OCT 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 ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	31 OCT 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 ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	01 NOV 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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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 ☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	02 NOV 2020

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	98.6 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☐
	Mild ☒
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	03 NOV 2020

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	97.5 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 ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	04 NOV 2020

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	97.5 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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 ☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	05 NOV 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	96.7 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	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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 ☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	06 NOV 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	97.8 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	☐

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

	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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

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	☐

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 14:25:06

Generated On: 10 Jun 2021 10:06:48

Date of Visit	2 NOV 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	2 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 14:25:06

Generated On: 10 Jun 2021 10:06:48

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 NOV 2020
Day 5	Yes	6 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	2 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 09:30
Height (xxx.x)	166.3 cm
Weight (xxx.x)	169 lb
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 NOV 2020

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

US3862128

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 NOV 2020

US3862128

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	22 FEB 2021

Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒

Folder OID	UNBLND_DECIDE

US3862128

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Date of updated informed consent (dd MMM yyyy) 22 FEB 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) 22 FEB 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 _____
Continuing with mRNA-1273 _____

US3862128

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Was the sample collected?	Yes ☒
	No ☐

Collection date (dd MMM yyyy)	22 FEB 2021

Collection time (00:00-23:59)	14:22 (24 HR)

Collection date and time (derived)	22 FEB 2021 14:22

US3862128

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 FEB 2021

Collection time (00:00 - 23:59)

14:21

Collection Date and Time (derived)

22 FEB 2021 14:21

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Apr 2021 21:42:54

Generated On: 10 Jun 2021 10:06:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

AEID	
Adverse event	EXACERBATION OF SEASONAL ALLERGIES
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)	19 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	5 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

AEID

Adverse event

PROLONGED INJECTION SITE
REACTION (REDNESS)

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) 02 OCT 2020

Start time (00:00-23:59) 20:08 (24 HR)

AE start date and time (derived) 02 OCT 2020 20:08

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 10 OCT 2020

End time (00:00-23:59) 22:10 (24 HR)

AE End Date and Time (derived) 10 OCT 2020 22:10

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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

AEID	USA-US121-2021-MRNA-1273-P30 1000008
Adverse event	DIVERTICULITIS
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)	25 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

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	True
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	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

70 Y/O FEMALE WITH PMH OF
DIVERTICULOSIS SINCE 2016
PRESENTED TO THE
MEMORIAL HERMANN
SATELLITE ER CLINICS IN
HUMBLE ON 26 APR 2021 WITH
SEVERE ABDOMINAL PAIN,
NAUSEA AND VOMITING. THE
PARTICIPANT STARTED
HAVING LOWER ABDOMINAL
PAIN (FELT LIKE BLADDER
SPASM) ON 25 APR 2021
FOLLOWED BY NAUSEA AND
VOMITING (QH30-40 MIN). BY
MIDAFTERNOON ON 26 APR
2021 THE ABDOMINAL PAIN
INCREASED IN SEVERITY
(10/10) AND WAS GENERALIZED
IN LOCATION. WHILE IN ER SHE
RECEIVED IV FLUID,
MORPHINE FOR PAIN AND
ONDANSETRON FOR NAUSEA.
SHE HAD A CT OF THE
ABDOMEN AND PELVIS WHICH
IDENTIFIED DIVERTICULITIS IN
THE SIGMOID COLON.
PREVIOUS COLONOSCOPY
DONE IN THE FALL 2020
INDICATED DIVERTICULA IN
THE COLON. SHE WAS
TRANSFERRED TO MEMORIAL
HERMANN NE WHERE SHE WAS
ADMITTED FOR TREATMENT
AND MONITORING. PER
PARTICIPANT' STATEMENT SHE
WILL BE DISCHARGED ON 29
APR 2021. MEDICAL RECORDS
WILL BE REQUESTED UPON
THE PARTICIPANT'S
DISCHARGE.

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

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:25:06

Generated On: 10 Jun 2021 10:06:48

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication LETROZOLE

Prophylaxis Yes ☐
No ☒

Indication BREAST CANCER

Dose per administration 2.5

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1987
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 ☒	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication ELEVATED CHOLESTEROL

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 ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication ACETAZOLAMIDE

Prophylaxis Yes ☐
No ☒

Indication ALTITUDE SICKNESS

Dose per administration 125

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
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	☐

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication OSTEOPENIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR GOOD HEALTH

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication OSTEOPENIA

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication METAMUCIL [PSYLLIUM FIBER]

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWEL DISEASE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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	☒

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication DENOSUMAB

Prophylaxis Yes ☐
No ☒

Indication OSTEOGENIA

Dose per administration 60

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 6 MONTHS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
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	☐

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SOLICITED SYMPTOMS: LOW
GRADE FEVER, PAIN

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 14:25:05

Generated On: 10 Jun 2021 10:06:48

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	03 OCT 2020	
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3862128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:25:06

Generated On: 10 Jun 2021 10:06:48

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

Visit	Screening	☐
	Visit 1 Day 1	☐
	Visit 2 Day 29	☐
	Visit 3 Day 57	☒
	Visit 4 Day 209	☐
	Visit 5 Day 394	☐
	Visit 6 Day 759	☐

Case Report Form

Visit Date	True
Demographics	True
Enrollment	True
Inclusion/Exclusion Criteria Summary	True
Inclusion/Exclusion Criteria	True
Medical History Summary	True
Medical History	True
Vital Signs	True
Vital Signs - Dosing	True
Physical Examination	True
Central Laboratory - Nasopharyngeal Swab	True
Childbearing Potential	False
Pregnancy Test	False
Randomization	True
Exposure	True
Immunogenicity Assessment	True
Saliva Collection	True
COVID Diagnostic Test	True
Symptom Log	True
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	True
COVID-19 Severity Assessment	False
COVID-19 Contact	True
Risk of Exposure	True
Safety Call	True
Dosing Discontinuation	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 02 Apr 2021 14:25:07

Generated On: 10 Jun 2021 10:06:48

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	2 NOV 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	True
Other, specify	ILLNESS VISIT
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	False
Symptoms of COVID-19	True
Sponsor hold due to COVID-19	False
Participant decision	False

US3862128

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:06:48

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

US3862128

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:06:48

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 ☐

US3862128

Folder: SAE-USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 16:54:14

Generated On: 10 Jun 2021 10:06:48

SAEID	USA-US121-2021-MRNA-1273-P301000008
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 16:54:14

Generated On: 10 Jun 2021 10:06:48

SAEID	USA-US121-2021-MRNA-1273-P301000008
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	29/APR/2021 06:11
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

US3862128 (Prod: Baylor College of Medicine)

US3862128

Form: Participant Creation

Generated On: 10 Jun 2021 10:06:48

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:31:43
User entered 'US3862128'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 15:24:28

US3862128

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:54:18
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:08

US3862128

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:54:18
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 15:24:29

US3862128

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:54:18
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:08

US3862128

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'SCRN'	System	04 Sep 2020 16:14:08

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:27
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 15:24:30

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:30
User entered '69'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'YEARS'	System	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '69'	System	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:31
User entered 'Female (F)'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:37
User entered '1'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:37
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:37
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:37
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:37
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:37
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:37
User entered empty.	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:37
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:06:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:37
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:03:29

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:47
User entered '4 Sep 2020'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Sep 2020'	System	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2020'	System	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:47
User entered 'Amendment 3 (3)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:47
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:47
User entered empty.	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:47
User entered empty.	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:47
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:55:47
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 15:24:29

US3862128

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:06:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '1'	System	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:31:56
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 17:53:56
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:56:07
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:11

US3862128

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:06:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
User closed query 'Other medical procedures have been added to source. Please confirm if these are significant or not significant and update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:49:43
Query 'Other medical procedures have been added to source. Please confirm if these are significant or not significant and update EDC accordingly. ' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4)	28 Oct 2020 21:01:20
User opened query 'Other medical procedures have been added to source. Please confirm if these are significant or not significant and update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:05:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:56:16
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	04 Sep 2020 16:14:31

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:56:52
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:11:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:11:52
Data point term sent to Coder	System	04 Sep 2020 17:07:29
User entered 'superficial leg blood clot'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:56:54
User entered 'un UNK 1985'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:00
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:05
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	31 Mar 2021 19:32:31
User signature succeeded.	(b) (4) Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:07
User entered 'un UNK 1985'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:09
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 1985'	System	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '1985'	System	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 1985'	System	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '1985'	System	04 Sep 2020 17:06:48

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:20
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 17:08:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 17:08:36
Data point term sent to Coder	System	04 Sep 2020 17:07:29
User entered 'acid reflux'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:21
User entered 'un UNK 2017'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:24
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:26
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:33
User entered empty.	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:34
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 2017'	System	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2017'	System	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	04 Sep 2020 17:07:02

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:57:52
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 17:08:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 17:08:36
Data point term sent to Coder	System	04 Sep 2020 17:07:29
User entered 'irritable bowel syndrome'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:54
User entered 'un UNK 2017'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:50
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:47
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:45
User entered empty.	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:57:44
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 2017'	System	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2017'	System	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	04 Sep 2020 17:07:26

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	19 Jan 2021 20:25:53
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Adverse drug reaction, LLT: Drug side effect - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 22:56:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 22:56:51
Data point term sent to Coder	System	03 Dec 2020 17:04:39
DataPoint Un-verified.	Trent Davis (b) (4)	03 Dec 2020 17:04:24
Coding entries removed.	(b) (4)	
	Trent Davis (b) (4)	03 Dec 2020 17:04:24
User entered 'MYALGIA AS SIDE EFFECT OF LETROZOLE' reason for change: Data Entry Error	(b) (4)	
User closed query 'Please update to one term and enter a log line or consolidate as one term. ' (Site from CRA).	Trent Davis (b) (4)	03 Dec 2020 17:04:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:04:34
	(b) (4), (b) (6)	30 Oct 2020 19:04:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4)	27 Oct 2020 18:11:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Query 'Please update to one term and enter a log line or consolidate as one term. ' answered with 'data corrected' (Site from CRA).	Shetel Anassi (b) (4)	27 Oct 2020 18:10:49
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	27 Oct 2020 18:10:27
	Shetel Anassi (b) (4)	27 Oct 2020 18:10:21
	(b) (4)	
User entered 'MYALGIA' reason for change: Data Entry Error	Shetel Anassi (b) (4)	27 Oct 2020 18:10:21
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 18:03:37

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:02:21
User opened query 'Please update to one term and enter a log line or consolidate as one term. ' (Site from CRA).		14 Oct 2020 17:00:16
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Adverse drug reaction, LLT: Drug side effect - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:24:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:24:53
Data point term sent to Coder	System	04 Sep 2020 17:12:42
User entered 'myalgia and arthalgias as a side effect of letrozole'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:03:45
DataPoint Un-verified.		14 Oct 2020 18:03:40
DataPoint Verified.		14 Oct 2020 17:00:20
User entered 'un UNK 2017'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:22
User entered '0'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:24
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 20:34:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 20:34:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:34:58
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 17:12:00
User entered empty.	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:00:25
User entered empty.	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	14 Oct 2020 17:00:27
User entered '0'	Sandra Francisco (b) (4)	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 2017'	System	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2017'	System	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	04 Sep 2020 17:12:00

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	14 Oct 2020 17:01:40
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4), (b) (6)	08 Sep 2020 20:50:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 20:50:53
Data point term sent to Coder	(b) (4)	08 Sep 2020 20:49:57
User entered 'Seasonal Allergies'	System	08 Sep 2020 20:49:23
	Trent Davis (b) (4)	
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
User closed query 'Per source, start date is un/unk/1995. Please update EDC accordingly. ' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:04:47
Query 'Per source, start date is un/unk/1995. Please update EDC accordingly. ' answered with 'Data corrected' (Site from CRA).	(b) (4), (b) (6)	
User entered 'un UNK 1995' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 19:04:43
DataPoint Un-verified.	Shetel Anassi (b) (4)	27 Oct 2020 18:11:26
DataPoint Verified.	(b) (4)	
User opened query 'Per source, start date is un/unk/1995. Please update EDC accordingly. ' (Site from CRA).	Shetel Anassi (b) (4)	27 Oct 2020 18:11:16
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:03:32
	(b) (4)	14 Oct 2020 18:02:21
	(b) (4)	14 Oct 2020 17:01:38
	Trent Davis (b) (4)	08 Sep 2020 20:49:23
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:04:45
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	27 Oct 2020 18:11:28
User entered '0' reason for change: Data Entry Error Shetel Anassi	(b) (4) (b) (4)	27 Oct 2020 18:11:28
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	27 Oct 2020 18:11:16
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:03:34
DataPoint Verified.		14 Oct 2020 18:02:21
User entered '1'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:49:23

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:01:44
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:49:23

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:01:45
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:49:23

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:01:48
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:49:23

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 1995'	System	27 Oct 2020 18:11:16
User entered empty.	System	08 Sep 2020 20:49:23

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '1995'	System	27 Oct 2020 18:11:16
User entered empty.	System	08 Sep 2020 20:49:23

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	08 Sep 2020 20:49:23

US3862128

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	08 Sep 2020 20:49:23

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
DataPoint Verified.	(b) (4)	14 Apr 2021 17:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Invasive ductal breast carcinoma, LLT: Invasive ductal breast carcinoma - version MedDRA\23.0.	(b) (4)	
	Coder Import (b) (4)	01 Apr 2021 11:15:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	31 Mar 2021 19:33:47
DataPoint Un-verified.	Carrie Kibler (b) (4)	31 Mar 2021 19:33:34
Coding entries removed.	(b) (4)	
	Carrie Kibler (b) (4)	31 Mar 2021 19:33:34
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	31 Mar 2021 19:33:34
User entered 'LEFT BREAST CANCER(invasive ductal carcinoma)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	31 Mar 2021 19:33:34
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 20:26:06
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\23.0.	Coder Import (b) (4)	02 Dec 2020 18:28:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Dec 2020 18:28:50
Data point term sent to Coder	System	02 Dec 2020 18:27:53
DataPoint Un-verified.	Trent Davis (b) (4)	02 Dec 2020 18:27:44
Coding entries removed.	(b) (4)	
	Trent Davis (b) (4)	02 Dec 2020 18:27:44
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
User entered 'Left BREAST CANCER' reason for change: Data Entry Error	Trent Davis (b) (4)	02 Dec 2020 18:27:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 18:03:26
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:03:10
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:02:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 21:14:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 21:14:55
Data point term sent to Coder	System	08 Sep 2020 21:13:49
User entered 'Breast Cancer'	Trent Davis (b) (4)	08 Sep 2020 21:13:16
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:03:28
DataPoint Un-verified.		14 Oct 2020 18:03:21
DataPoint Verified.		14 Oct 2020 18:02:21
User entered 'un May 2017'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:13:16

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:06
DataPoint Un-verified.		14 Oct 2020 18:03:20
DataPoint Verified.		14 Oct 2020 18:02:21
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:13:16

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:06
DataPoint Un-verified.		14 Oct 2020 18:03:19
DataPoint Verified.		14 Oct 2020 18:02:21
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:13:16

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:06
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	05 Nov 2020 17:29:37
User entered 'UN Jan 2018' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	05 Nov 2020 17:29:37
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	30 Oct 2020 18:20:58
User entered 'un UNK 2017' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	30 Oct 2020 18:20:58
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:03:15
DataPoint Verified.		14 Oct 2020 18:02:21
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:13:16

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:06
User closed query 'Per DM CLR: Stop date is recorded for this condition. However, there is no corresponding procedure recorded that would lead to the treatment of this condition. Please add the corresponding treatment in the MH page. Otherwise, please provide clarification on the stop date recorded.' (Site from DM).		04 Nov 2020 09:42:25
User entered '0' reason for change: New Information	Sandra Francisco (b) (4)	30 Oct 2020 18:20:58
Query 'Per DM CLR: Stop date is recorded for this condition. However, there is no corresponding procedure recorded that would lead to the treatment of this condition. Please add the corresponding treatment in the MH page. Otherwise, please provide clarification on the stop date recorded.' answered with 'Data corrected' (Site from DM).	(b) (4) Shetel Anassi (b) (4) (b) (4)	28 Oct 2020 20:52:50
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:03:17
DataPoint Verified.		14 Oct 2020 18:02:21
User opened query 'Per DM CLR: Stop date is recorded for this condition. However, there is no corresponding procedure recorded that would lead to the treatment of this condition. Please add the corresponding treatment in the MH page. Otherwise, please provide clarification on the stop date recorded.' (Site from DM).		13 Oct 2020 10:43:18
User entered '1'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:13:16

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'May 2017'	System	08 Sep 2020 21:13:16

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2017'	System	08 Sep 2020 21:13:16

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 2018'	System	05 Nov 2020 17:29:37
User entered 'Jan 2017'	System	30 Oct 2020 18:20:58
User entered empty.	System	08 Sep 2020 21:13:16

US3862128

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2018'	System	05 Nov 2020 17:29:37
User entered '2017'	System	30 Oct 2020 18:20:58
User entered empty.	System	08 Sep 2020 21:13:16

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
DataPoint Verified.	(b) (4)	14 Apr 2021 17:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Acute and chronic thyroiditis, PT: Autoimmune thyroiditis, LLT: Hashimoto's thyroiditis - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 19:35:13
Data point term sent to Coder	(b) (4)	
DataPoint Un-verified.	Coder Import (b) (4)	31 Mar 2021 19:35:13
Coding entries removed.	System	31 Mar 2021 19:34:48
Signature has been broken.	Carrie Kibler (b) (4)	31 Mar 2021 19:34:07
User entered 'HASHIMOTO's HYPOTHYROIDISM' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Carrie Kibler (b) (4)	31 Mar 2021 19:34:07
DataPoint Verified.	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Acute and chronic thyroiditis, PT: Autoimmune thyroiditis, LLT: Hashimoto's thyroiditis - version MedDRA\23.0.	Carrie Kibler (b) (4)	31 Mar 2021 19:34:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Carrie Kibler (b) (4)	31 Mar 2021 19:34:07
User entered 'hashimoto hypothyroidism'	(b) (4)	
	Thea Marie Cordero	29 Mar 2021 15:57:09
	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 17:59:08
	Coder Import (b) (4)	09 Sep 2020 09:05:34
	(b) (4)	
	Coder Import (b) (4)	09 Sep 2020 09:05:34
	(b) (4)	
	System	08 Sep 2020 21:14:52
	Trent Davis (b) (4)	08 Sep 2020 21:14:22
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
User closed query 'Per source, start date is un/unk/1987. Please update EDC accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:05:06
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:05:04
Query 'Per source, start date is un/unk/1987. Please update EDC accordingly.' answered with 'Data corrected' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 18:13:53
User entered 'un UNK 1987' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 18:13:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:02:37
DataPoint Verified.		14 Oct 2020 18:02:21
User opened query 'Per source, start date is un/unk/1987. Please update EDC accordingly.' (Site from CRA).		14 Oct 2020 17:59:37
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 17:59:26
DataPoint Verified.		14 Oct 2020 17:59:24
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:14:22

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:05:07
User entered '0' reason for change: Data Entry Error	Shetel Anassi (b) (4)	27 Oct 2020 18:13:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:02:39
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:02:21
Query 'Per source, start date is un/unk/1987. Please update EDC accordingly. ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 17:59:22
User opened query 'Per source, start date is un/unk/1987. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 17:58:39
User entered '1'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:14:22

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:59:40
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:14:22

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:58:45
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:14:22

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:58:48
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:14:22

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 1987'	System	27 Oct 2020 18:13:46
User entered empty.	System	08 Sep 2020 21:14:22

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '1987'	System	27 Oct 2020 18:13:46
User entered empty.	System	08 Sep 2020 21:14:22

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	08 Sep 2020 21:14:22

US3862128

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	08 Sep 2020 21:14:22

US3862128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:00:00
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: Cholesterol high - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:16:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:16:59
Data point term sent to Coder	System	08 Sep 2020 21:15:53
User entered 'Elevated Cholesterol'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:15:52

US3862128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
User closed query 'Per source, start date is entered as un/unk/2014. Please update EDC accordingly. ' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:05:17
Query 'Per source, start date is entered as un/unk/2014. Please update EDC accordingly. ' answered with 'Data corrected' (Site from CRA).	(b) (4), (b) (6)	
User entered 'un UNK 2014' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 19:05:14
DataPoint Un-verified.	Shetel Anassi (b) (4)	27 Oct 2020 18:15:10
DataPoint Verified.	(b) (4)	
User opened query 'Per source, start date is entered as un/unk/2014. Please update EDC accordingly. ' (Site from CRA).	Shetel Anassi (b) (4)	27 Oct 2020 18:15:02
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 18:02:31
		14 Oct 2020 18:02:21
		14 Oct 2020 18:00:34
	Trent Davis (b) (4)	08 Sep 2020 21:15:52
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:05:15
User entered '0' reason for change: Data Entry Error	Shetel Anassi (b) (4)	27 Oct 2020 18:15:02
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:02:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:02:21
User entered '1'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:15:52

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:00:36
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:15:52

US3862128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:00:38
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:15:52

US3862128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:00:39
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:15:52

US3862128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 2014'	System	27 Oct 2020 18:15:02
User entered empty.	System	08 Sep 2020 21:15:52

US3862128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2014'	System	27 Oct 2020 18:15:02
User entered empty.	System	08 Sep 2020 21:15:52

US3862128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	08 Sep 2020 21:15:52

US3862128

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	08 Sep 2020 21:15:52

US3862128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:00:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:19:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 21:19:01
Data point term sent to Coder	System	08 Sep 2020 21:17:58
User entered 'Osteopenia'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:17:31

US3862128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
User closed query 'Per source, start date is un/unk/2005. Please update EDC accordingly. ' (Site from CRA).	(b) (4)	30 Oct 2020 19:05:25
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:05:24
Query 'Per source, start date is un/unk/2005. Please update EDC accordingly. ' answered with 'Data COrrected' (Site from CRA).	Shetel Anassi (b) (4)	27 Oct 2020 18:13:12
User entered 'un UNK 2005' reason for change:	Shetel Anassi (b) (4)	27 Oct 2020 18:13:05
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:02:27
DataPoint Verified.		14 Oct 2020 18:02:21
User opened query 'Per source, start date is un/unk/2005. Please update EDC accordingly. ' (Site from CRA).		14 Oct 2020 18:01:27
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:17:31
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	30 Oct 2020 19:05:27
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 18:13:15
User entered '0' reason for change: Data Entry Error Shetel Anassi	(b) (4)	27 Oct 2020 18:13:15
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	27 Oct 2020 18:13:05
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:02:26
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:02:21
User entered '1'	Trent Davis (b) (4)	08 Sep 2020 21:17:31
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:01:55
DataPoint Un-verified.		14 Oct 2020 18:01:53
DataPoint Verified.		14 Oct 2020 18:01:30
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:17:31

US3862128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:01:56
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:17:31

US3862128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:01:58
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:17:31

US3862128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 2005'	System	27 Oct 2020 18:13:05
User entered empty.	System	08 Sep 2020 21:17:31

US3862128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2005'	System	27 Oct 2020 18:13:05
User entered empty.	System	08 Sep 2020 21:17:31

US3862128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	08 Sep 2020 21:17:31

US3862128

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	08 Sep 2020 21:17:31

US3862128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	14 Oct 2020 18:02:21
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4), (b) (6)	30 Sep 2020 22:59:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 22:59:45
Data point term sent to Coder	(b) (4)	30 Sep 2020 22:58:10
User entered 'Post Menopausal'	System	30 Sep 2020 22:57:47
	Chanei Henry (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:02:21
User entered 'un UNK 1999'	Chanei Henry (b) (4) (b) (4)	30 Sep 2020 22:57:47

US3862128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:02:21
User entered '0'	Chanei Henry (b) (4) (b) (4)	30 Sep 2020 22:57:47

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:02:21
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	30 Sep 2020 22:57:47

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:02:21
User entered empty.	Chanei Henry (b) (4) (b) (4)	30 Sep 2020 22:57:47

US3862128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:02:21
User entered '0'	Chanei Henry (b) (4) (b) (4)	30 Sep 2020 22:57:47

US3862128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 1999'	System	30 Sep 2020 22:57:47

US3862128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '1999'	System	30 Sep 2020 22:57:47

US3862128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	30 Sep 2020 22:57:47

US3862128

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	30 Sep 2020 22:57:47

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:25:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Adverse drug reaction, LLT: Drug side effect - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:15:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:15:55
Data point term sent to Coder	System	03 Dec 2020 17:04:37
Coding entries removed.	Trent Davis (b) (4) (b) (4)	03 Dec 2020 17:03:57
User entered 'ARTHALGIAS as side effect of letrozole' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	03 Dec 2020 17:03:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:23:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:23:33
Data point term sent to Coder	System	27 Oct 2020 18:11:31
User entered 'ARTHALGIAS'	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 18:10:36

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	19 Jan 2021 20:25:09
User entered 'un UNK 2017'	(b) (4), (b) (6)	19 Jan 2021 20:25:09
	Shetel Anassi (b) (4)	27 Oct 2020 18:10:36
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:25:09
User entered '0'	Shetel Anassi (b) (4)	27 Oct 2020 18:10:36

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:25:09
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 18:10:36

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:25:09
User entered empty.	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 18:10:36

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	19 Jan 2021 20:25:09
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:25:09
	Shetel Anassi (b) (4)	27 Oct 2020 18:10:36
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 2017'	System	27 Oct 2020 18:10:36

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2017'	System	27 Oct 2020 18:10:36

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	27 Oct 2020 18:10:36

US3862128

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	27 Oct 2020 18:10:36

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	19 Jan 2021 20:25:31
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries by physical agents, HLT: Atmospheric pressure injuries, PT: Hypobarism, LLT: Altitude sickness - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 20:07:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 20:07:32
Data point term sent to Coder	System	28 Oct 2020 20:53:02
User entered 'ALTITUDE SICKNESS'	Shetel Anassi (b) (4)	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:25:31
User entered 'un UNK 2008'	Shetel Anassi (b) (4)	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:25:31
User entered '0'	Shetel Anassi (b) (4)	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:25:31
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:25:31
User entered empty.	Shetel Anassi (b) (4)	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:25:31
User entered '0'	Shetel Anassi (b) (4)	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 2008'	System	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2008'	System	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	28 Oct 2020 20:52:12

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
DataPoint Verified.	(b) (4)	14 Apr 2021 17:28:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 14:02:38
Data point term sent to Coder	(b) (4)	
DataPoint Un-verified.	Coder Import (b) (4)	01 Apr 2021 14:02:38
	(b) (4)	
	System	31 Mar 2021 19:32:43
Coding entries removed.	Carrie Kibler (b) (4)	31 Mar 2021 19:32:01
	(b) (4)	
Signature has been broken.	Carrie Kibler (b) (4)	31 Mar 2021 19:32:01
	(b) (4)	
User entered 'ALLERGY TO ANESTHESIA MEDICATION(transaminitis)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	31 Mar 2021 19:32:01
User signature succeeded.	(b) (4)	
	Thea Marie Cordero	29 Mar 2021 15:57:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:26:46
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 03:18:11
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 03:18:11
Data point term sent to Coder	(b) (4)	
User entered 'Allergy to anesthesia medication'	System	28 Oct 2020 21:12:49
	Shetel Anassi (b) (4)	28 Oct 2020 21:11:59
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:46
User entered 'un UNK 2013'	Shetel Anassi (b) (4) (b) (4)	28 Oct 2020 21:11:59

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4)	19 Jan 2021 20:26:46
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:26:46
	Shetel Anassi (b) (4)	28 Oct 2020 21:11:59
	(b) (4)	

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:26:46
User entered 'Yes (Y)'	Shetel Anassi (b) (4)	28 Oct 2020 21:11:59

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:46
User entered empty.	Shetel Anassi (b) (4) (b) (4)	28 Oct 2020 21:11:59

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:46
User entered '0'	Shetel Anassi (b) (4) (b) (4)	28 Oct 2020 21:11:59

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'Jan 2013'	System	28 Oct 2020 21:11:59

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '2013'	System	28 Oct 2020 21:11:59

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	28 Oct 2020 21:11:59

US3862128

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:06:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered empty.	System	28 Oct 2020 21:11:59

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:21
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:33
User entered '04 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:34
User entered '09:51'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '04 Sep 2020 09:51'	System	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:36
User entered '166.3' cm	Sandra Francisco (b) (4)	04 Sep 2020 17:05:39
DataPoint set to visible.	(b) (4) System	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:39
User entered '169' lb	Sandra Francisco (b) (4)	04 Sep 2020 17:05:39
DataPoint set to visible.	(b) (4) System	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered '27.77663'	System	04 Sep 2020 17:05:39
DataPoint set to visible.	System	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'kg/m2'	System	04 Sep 2020 17:05:39
DataPoint set to visible.	System	04 Sep 2020 16:14:20

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:41
User entered '98.3' F	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:43
User entered 'Oral (Oral)'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:32:33
User entered empty.	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:54
User entered '68'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'bpm'	System	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:56
User entered '16'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'breaths/min'	System	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:13:58
User entered '158'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'mmHg'	System	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:14:00
User entered '88'	Sandra Francisco (b) (4) (b) (4)	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User entered 'mmHg'	System	04 Sep 2020 17:05:39

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36

US3862128

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36

US3862128

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User closed query 'Per source, abnormalities are noted, however, it doesn't indicate if these are CS or NCS. Please confirm if these should be entered in EDC. ' (Site from CRA).		23 Feb 2021 06:24:42
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
	(b) (4)	
Query 'Per source, abnormalities are noted, however, it doesn't indicate if these are CS or NCS. Please confirm if these should be entered in EDC. ' answered with 'NCS' (Site from CRA).	Shetel Anassi (b) (4)	27 Oct 2020 17:59:25
	(b) (4)	
User opened query 'Per source, abnormalities are noted, however, it doesn't indicate if these are CS or NCS. Please confirm if these should be entered in EDC. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:12:29
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:10:55
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	04 Sep 2020 16:14:27
	(b) (4)	

US3862128

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:10:57
User entered '4 Sep 2020'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:27

US3862128

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:41
User entered '4 Sep 2020'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:47:33

US3862128

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:48

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:42
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:47:33

US3862128

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:48

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:09:47
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:15:20
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'Added to MH' (Site from DM).	Chanei Henry (b) (4)	30 Sep 2020 22:55:18
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:23:54
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Trent Davis (b) (4)	08 Sep 2020 20:47:33

US3862128

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:48

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:51
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:47:33

US3862128

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:48

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:52
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:47:33

US3862128

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:48

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:55
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:47:33

US3862128

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:48

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
User closed query 'Per source, date of last menstruation was un/unk/1999. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 15:17:35
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:17:31
Query 'Per source, date of last menstruation was un/unk/1999. Please update EDC accordingly. ' answered with 'Data corrected' (Site from CRA).	Shetel Anassi (b) (4)	27 Oct 2020 17:58:59
User closed query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	27 Oct 2020 17:58:51
User opened query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	27 Oct 2020 17:56:46
User entered 'un UNK 1999' reason for change: Data Entry Error	Shetel Anassi (b) (4)	27 Oct 2020 17:56:46
User opened query 'Per source, date of last menstruation was un/unk/1999. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:10:29
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 20:47:33

US3862128

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:06:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:17:37
User entered '0' reason for change: Data Entry Error	Shetel Anassi (b) (4)	27 Oct 2020 17:58:51
User entered '1'	(b) (4) Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:47:33

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:39
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:41
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:42
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:44
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:46
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:47
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:49
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:51
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:52
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:53
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:55
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:29
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:08:31
User entered 'health administration'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:15
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:13
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:11
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

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)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:10
User entered '0'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:07
User entered '1'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:06:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:53:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:09:09
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:48:41

US3862128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:14:12
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:39

US3862128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	14 Oct 2020 18:14:14
User entered '4 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 18:14:14
	Carrie Kibler (b) (4)	04 Sep 2020 16:14:39
	(b) (4)	

US3862128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:14:16
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:39

US3862128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered 'VISIT1'	System	04 Sep 2020 16:14:39

US3862128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:48

[What was the date of randomization? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:15:05
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 16:04:38

US3862128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:48

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	14 Oct 2020 18:15:07
User entered '189693'	(b) (4), (b) (6)	14 Oct 2020 18:15:07
	RWS_ENDPOINT	04 Sep 2020 16:04:38
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:48

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:15:09
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	04 Sep 2020 16:04:38

US3862128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:48

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:15:52
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 23:35:05

US3862128

Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	14 Oct 2020 18:15:52
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:15:52
	Carrie Kibler (b) (4)	04 Sep 2020 23:35:05
	(b) (4)	

US3862128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:48

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:15:52
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 23:35:05

US3862128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:48

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:15:52
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 23:35:05

US3862128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:15:52
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 23:35:05

US3862128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:06:48

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:15:52
User entered 'No (N)'	Carrie Kibler (b) (4)	22 Sep 2020 18:37:42
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:23:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:23:42

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:32:52
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).		22 Oct 2020 15:09:33
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:13:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:13:15
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:38:00
User entered '166.3' cm	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:32:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:13:15
User entered '169.0' lb	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:32:52
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).		22 Oct 2020 15:09:33
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:13:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:13:15
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:38:00
User entered '166.3' cm	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:32:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 17:13:15
User entered '169.0' lb	Trent Davis (b) (4)	09 Sep 2020 14:59:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:16:38
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:16:38
User entered '4 Sep 2020'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:16:38
User entered '09:51'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered '4 Sep 2020 09:51'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:16:38
User entered '98.3' F	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:16:38
User entered 'Oral (Oral)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:16:38
User entered empty.	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:16:38
User entered '068'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered 'bpm'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:16:38
User entered '016'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered 'breaths/min'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:38
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 16:10:24
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Trent Davis (b) (4)	09 Sep 2020 15:01:59
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	09 Sep 2020 14:59:31
User entered '158'	Trent Davis (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered 'mmHg'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:38
User entered '088'	Trent Davis (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered 'mmHg'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:32:52
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:09:33
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 17:13:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:13:15
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:38:00
User entered '166.3' cm	Trent Davis (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:06:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 17:32:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:13:15
User entered '169.0' lb	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered '4 Sep 2020'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered '12:10'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered '4 Sep 2020 12:10'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered '97.5' F	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered 'Oral (Oral)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered empty.	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered '064'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered 'bpm'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered '020'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered 'breaths/min'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered '137'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered 'mmHg'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:51
User entered '091'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User entered 'mmHg'	System	09 Sep 2020 14:59:31

US3862128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:59:50
User closed query 'Please remove as this was captured at time of screening. ' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 16:48:31
Query 'Please remove as this was captured at time of screening. ' answered with 'data corrected' (Site from CRA).	Trent Davis (b) (4)	20 Oct 2020 17:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:17:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 17:17:29
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	20 Oct 2020 17:17:29
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:17:25
User entered empty; reason for change Data Entry Error	Trent Davis (b) (4)	20 Oct 2020 17:17:25
User opened query 'Please remove as this was captured at time of screening. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:21:18
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	04 Sep 2020 16:14:47

US3862128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:48:06
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:59:52
User entered empty; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 17:17:25
User entered '4 Sep 2020'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:47

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:22
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 16:41:26

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 16:41:26

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:25
User entered empty.	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 16:41:26

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 16:41:26

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:21:35
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:21:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:21:28
User entered '4 Sep 2020'	Chanei Henry (b) (4)	04 Sep 2020 16:41:26
	(b) (4)	

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:37
User entered '11:37'	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 16:41:26

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User entered '4 Sep 2020 11:37'	System	04 Sep 2020 16:41:26

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:38
User entered 'Right Arm (RIGHT ARM)'	Chanei Henry (b) (4) (b) (4)	04 Sep 2020 16:41:26

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
DataPoint Verified.		14 Oct 2020 18:21:40
User entered 'ONCE'	System	04 Sep 2020 16:41:26

US3862128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 16:41:26

US3862128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:22:47
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:04:41

US3862128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:22:49
User entered '4 Sep 2020'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:04:41

US3862128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:22:50
User entered '10:38'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:04:41

US3862128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User entered '4 Sep 2020 10:38'	System	09 Sep 2020 15:04:41

US3862128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:06:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:22:58
User entered '4 Sep 2020'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:14:33

US3862128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4)	09 Sep 2020 15:14:33

US3862128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:05
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:14:33

US3862128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:05
User entered '10:15'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:14:33

US3862128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User entered '4 Sep 2020 10:15'	System	09 Sep 2020 15:14:33

US3862128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:14:33

US3862128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:08
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:14:33

US3862128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:08
User entered empty.	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:14:33

US3862128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User entered empty.	System	09 Sep 2020 15:14:33

US3862128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:12
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	04 Sep 2020 16:14:51

US3862128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User entered '1'	System	04 Sep 2020 16:14:51

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T12:05:07', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '864e4bcb-f7ae-4825-9744-fdc99d059e00'	System	04 Sep 2020 17:06:37
User entered 'Yes (Y)'	System	04 Sep 2020 17:06:37

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T12:06:24', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '864e4bcb-f7ae-4825-9744-fdc99d059e00'	System	04 Sep 2020 17:06:37
User entered '97.5'	System	04 Sep 2020 17:06:37

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T12:06:27', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '864e4bcb-f7ae-4825-9744-fdc99d059e00'	System	04 Sep 2020 17:06:37
User entered 'No (N)'	System	04 Sep 2020 17:06:37

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T12:06:34', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '864e4bcb-f7ae-4825-9744-fdc99d059e00'	System	04 Sep 2020 17:06:37
User entered '04 Sep 2020 12:06'	System	04 Sep 2020 17:06:37

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Sep 2020 11:57'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Sep 2020 14:27'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:35:27', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '93a0c2bf-2816-468b-9551-9bf52e95d31f'	System	05 Sep 2020 00:35:52
User entered 'Yes (Y)'	System	05 Sep 2020 00:35:52

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:35:41', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '93a0c2bf-2816-468b-9551-9bf52e95d31f' User entered '97.8'	System	05 Sep 2020 00:35:52

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:35:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '93a0c2bf-2816-468b-9551-9bf52e95d31f'	System	05 Sep 2020 00:35:52
User entered 'No (N)'	System	05 Sep 2020 00:35:52

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:35:49', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '93a0c2bf-2816-468b-9551-9bf52e95d31f' User entered '04 Sep 2020 19:35'	System	05 Sep 2020 00:35:52
	System	05 Sep 2020 00:35:52

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Sep 2020 15:22'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 2'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:19:29', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5ad400ee-156e-4f0e-9552-03e255d4bd8c'	System	06 Sep 2020 02:19:49
User entered 'Yes (Y)'	System	06 Sep 2020 02:19:49

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:19:39', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5ad400ee-156e-4f0e-9552-03e255d4bd8c'	System	06 Sep 2020 02:19:49
User entered '98.3'	System	06 Sep 2020 02:19:49

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:19:44', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5ad400ee-156e-4f0e-9552-03e255d4bd8c'	System	06 Sep 2020 02:19:49
User entered 'No (N)'	System	06 Sep 2020 02:19:49

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:19:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5ad400ee-156e-4f0e-9552-03e255d4bd8c'	System	06 Sep 2020 02:19:49
User entered '05 Sep 2020 21:19'	System	06 Sep 2020 02:19:49

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 3'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:08:53', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '3942fb6b-acfe-4819-9431-8f9b2a71122f'	System	07 Sep 2020 01:09:12
User entered 'Yes (Y)'	System	07 Sep 2020 01:09:12

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:03', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '3942fb6b-acfe-4819-9431-8f9b2a71122f' User entered '98.2'	System	07 Sep 2020 01:09:12
	System	07 Sep 2020 01:09:12

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '3942fb6b-acfe-4819-9431-8f9b2a71122f'	System	07 Sep 2020 01:09:12
User entered 'No (N)'	System	07 Sep 2020 01:09:12

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '3942fb6b-acfe-4819-9431-8f9b2a71122f'	System	07 Sep 2020 01:09:12
User entered '06 Sep 2020 20:09'	System	07 Sep 2020 01:09:12

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 4'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:04', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '376100c9-20fa-438f-95dd-9483c0346653'	System	07 Sep 2020 22:58:24
User entered 'Yes (Y)'	System	07 Sep 2020 22:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '376100c9-20fa-438f-95dd-9483c0346653' User entered '97.3'	System	07 Sep 2020 22:58:24
	System	07 Sep 2020 22:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:15', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '376100c9-20fa-438f-95dd-9483c0346653'	System	07 Sep 2020 22:58:24
User entered 'No (N)'	System	07 Sep 2020 22:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:21', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '376100c9-20fa-438f-95dd-9483c0346653'	System	07 Sep 2020 22:58:24
User entered '07 Sep 2020 17:58'	System	07 Sep 2020 22:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 5'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:21:42', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a4af7ebb-6a65-4131-9f58-3440e82ba6d7'	System	09 Sep 2020 03:22:00
User entered 'Yes (Y)'	System	09 Sep 2020 03:22:00

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:21:49', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a4af7ebb-6a65-4131-9f58-3440e82ba6d7'	System	09 Sep 2020 03:22:00
User entered '97.6'	System	09 Sep 2020 03:22:00

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:21:53', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a4af7ebb-6a65-4131-9f58-3440e82ba6d7'	System	09 Sep 2020 03:22:00
User entered 'No (N)'	System	09 Sep 2020 03:22:00

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:21:56', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a4af7ebb-6a65-4131-9f58-3440e82ba6d7'	System	09 Sep 2020 03:22:00
User entered '08 Sep 2020 22:21'	System	09 Sep 2020 03:22:00

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 6'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:53:20', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '677cfeb8-fd4f-4af8-aa6d-175ae3cb9c27'	System	09 Sep 2020 23:53:33
User entered 'Yes (Y)'	System	09 Sep 2020 23:53:33

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:53:25', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '677cfeb8-fd4f-4af8-aa6d-175ae3cb9c27'	System	09 Sep 2020 23:53:33
User entered '98.6'	System	09 Sep 2020 23:53:33

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:53:28', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '677cfeb8-fd4f-4af8-aa6d-175ae3cb9c27'	System	09 Sep 2020 23:53:33
User entered 'No (N)'	System	09 Sep 2020 23:53:33

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:53:30', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '677cfeb8-fd4f-4af8-aa6d-175ae3cb9c27'	System	09 Sep 2020 23:53:33
User entered '09 Sep 2020 18:53'	System	09 Sep 2020 23:53:33

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 7'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:44:41', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '17987b4e-47a0-4cba-8f0f-0a080c157a69'	System	10 Sep 2020 23:44:57
User entered 'Yes (Y)'	System	10 Sep 2020 23:44:57

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:44:47', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '17987b4e-47a0-4cba-8f0f-0a080c157a69' User entered '96.4'	System	10 Sep 2020 23:44:57
	System	10 Sep 2020 23:44:57

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:44:51', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '17987b4e-47a0-4cba-8f0f-0a080c157a69'	System	10 Sep 2020 23:44:57
User entered 'No (N)'	System	10 Sep 2020 23:44:57

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:44:53', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '17987b4e-47a0-4cba-8f0f-0a080c157a69'	System	10 Sep 2020 23:44:57
User entered '10 Sep 2020 17:44'	System	10 Sep 2020 23:44:57

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:58:32', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '3cfdb0cf-0aa0-4a3c-bd07-8cb95656b344'	System	04 Sep 2020 16:59:14
User entered 'None (1)'	System	04 Sep 2020 16:59:14

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:58:59', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '3cfdb0cf-0aa0-4a3c-bd07-8cb95656b344'	System	04 Sep 2020 16:59:14
User entered 'No (N)'	System	04 Sep 2020 16:59:14

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:59:04', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '3cfdb0cf-0aa0-4a3c-bd07-8cb95656b344'	System	04 Sep 2020 16:59:14
User entered 'No (N)'	System	04 Sep 2020 16:59:14

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:59:08', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '3cfdb0cf-0aa0-4a3c-bd07-8cb95656b344'	System	04 Sep 2020 16:59:14
User entered 'None (1)'	System	04 Sep 2020 16:59:14

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:59:12', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '3cfdb0cf-0aa0-4a3c-bd07-8cb95656b344'	System	04 Sep 2020 16:59:14
User entered '04 Sep 2020 11:59'	System	04 Sep 2020 16:59:14

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Sep 2020 11:57'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Sep 2020 14:27'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:32:33', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'de56444a-0ab0-4402-957e-91db8ff97874'	System	05 Sep 2020 00:34:07
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 00:34:07

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:32:39', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'de56444a-0ab0-4402-957e-91db8ff97874'	System	05 Sep 2020 00:34:07
User entered 'Yes (Y)'	System	05 Sep 2020 00:34:07

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:33:43', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'de56444a-0ab0-4402-957e-91db8ff97874' User entered '3'	System	05 Sep 2020 00:34:07
	System	05 Sep 2020 00:34:07

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:33:47', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'de56444a-0ab0-4402-957e-91db8ff97874'	System	05 Sep 2020 00:34:07
User entered 'Yes (Y)'	System	05 Sep 2020 00:34:07

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:33:54', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'de56444a-0ab0-4402-957e-91db8ff97874' User entered '15'	System	05 Sep 2020 00:34:07

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:33:59', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'de56444a-0ab0-4402-957e-91db8ff97874'	System	05 Sep 2020 00:34:07
User entered 'None (1)'	System	05 Sep 2020 00:34:07

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:34:04', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'de56444a-0ab0-4402-957e-91db8ff97874'	System	05 Sep 2020 00:34:07
User entered '04 Sep 2020 19:34'	System	05 Sep 2020 00:34:07

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Sep 2020 15:22'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 2'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:49', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '38836b11-3449-49af-8ddc-d69e515a06cb'	System	06 Sep 2020 02:19:26
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 02:19:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:53', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '38836b11-3449-49af-8ddc-d69e515a06cb'	System	06 Sep 2020 02:19:26
User entered 'Yes (Y)'	System	06 Sep 2020 02:19:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:19:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '38836b11-3449-49af-8ddc-d69e515a06cb' User entered '3'	System	06 Sep 2020 02:19:26
	System	06 Sep 2020 02:19:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:19:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '38836b11-3449-49af-8ddc-d69e515a06cb'	System	06 Sep 2020 02:19:26
User entered 'Yes (Y)'	System	06 Sep 2020 02:19:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:19:15', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '38836b11-3449-49af-8ddc-d69e515a06cb' User entered '15'	System	06 Sep 2020 02:19:26
	System	06 Sep 2020 02:19:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:19:19', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '38836b11-3449-49af-8ddc-d69e515a06cb'	System	06 Sep 2020 02:19:26
User entered 'None (1)'	System	06 Sep 2020 02:19:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:19:22', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '38836b11-3449-49af-8ddc-d69e515a06cb'	System	06 Sep 2020 02:19:26
User entered '05 Sep 2020 21:19'	System	06 Sep 2020 02:19:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 3'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:15', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '24b65a76-5400-43bf-a709-fa8e2e9b664c'	System	07 Sep 2020 01:09:37
User entered 'None (1)'	System	07 Sep 2020 01:09:37

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:19', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '24b65a76-5400-43bf-a709-fa8e2e9b664c'	System	07 Sep 2020 01:09:37
User entered 'No (N)'	System	07 Sep 2020 01:09:37

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:22', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '24b65a76-5400-43bf-a709-fa8e2e9b664c'	System	07 Sep 2020 01:09:37
User entered 'No (N)'	System	07 Sep 2020 01:09:37

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:26', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '24b65a76-5400-43bf-a709-fa8e2e9b664c'	System	07 Sep 2020 01:09:37
User entered 'None (1)'	System	07 Sep 2020 01:09:37

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:31', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '24b65a76-5400-43bf-a709-fa8e2e9b664c'	System	07 Sep 2020 01:09:37
User entered '06 Sep 2020 20:09'	System	07 Sep 2020 01:09:37

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 4'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:26', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5a16acb9-b2f8-4b67-9e16-cc0e3205dc24'	System	07 Sep 2020 22:58:47
User entered 'None (1)'	System	07 Sep 2020 22:58:47

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:28', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5a16acb9-b2f8-4b67-9e16-cc0e3205dc24'	System	07 Sep 2020 22:58:47
User entered 'No (N)'	System	07 Sep 2020 22:58:47

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:32', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5a16acb9-b2f8-4b67-9e16-cc0e3205dc24'	System	07 Sep 2020 22:58:47
User entered 'No (N)'	System	07 Sep 2020 22:58:47

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:35', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5a16acb9-b2f8-4b67-9e16-cc0e3205dc24'	System	07 Sep 2020 22:58:47
User entered 'None (1)'	System	07 Sep 2020 22:58:47

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:42', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5a16acb9-b2f8-4b67-9e16-cc0e3205dc24'	System	07 Sep 2020 22:58:47
User entered '07 Sep 2020 17:58'	System	07 Sep 2020 22:58:47

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 5'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:02', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'e85ce006-a7c2-40b8-9df6-baef94f3918f'	System	09 Sep 2020 03:22:16
User entered 'None (1)'	System	09 Sep 2020 03:22:16

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:04', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'e85ce006-a7c2-40b8-9df6-baef94f3918f' User entered 'No (N)'	System	09 Sep 2020 03:22:16
	System	09 Sep 2020 03:22:16

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:07', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'e85ce006-a7c2-40b8-9df6-baef94f3918f'	System	09 Sep 2020 03:22:16
User entered 'No (N)'	System	09 Sep 2020 03:22:16

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'e85ce006-a7c2-40b8-9df6-baef94f3918f'	System	09 Sep 2020 03:22:16
User entered 'None (1)'	System	09 Sep 2020 03:22:16

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:13', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'e85ce006-a7c2-40b8-9df6-baef94f3918f' User entered '08 Sep 2020 22:22'	System	09 Sep 2020 03:22:16
	System	09 Sep 2020 03:22:16

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 6'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:53:02', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '39e6ebc7-97c1-4492-8885-7c2a1e65ae08'	System	09 Sep 2020 23:53:17
User entered 'None (1)'	System	09 Sep 2020 23:53:17

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:53:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '39e6ebc7-97c1-4492-8885-7c2a1e65ae08'	System	09 Sep 2020 23:53:17
User entered 'No (N)'	System	09 Sep 2020 23:53:17

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:53:08', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '39e6ebc7-97c1-4492-8885-7c2a1e65ae08'	System	09 Sep 2020 23:53:17
User entered 'No (N)'	System	09 Sep 2020 23:53:17

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:53:11', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '39e6ebc7-97c1-4492-8885-7c2a1e65ae08'	System	09 Sep 2020 23:53:17
User entered 'None (1)'	System	09 Sep 2020 23:53:17

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:53:13', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '39e6ebc7-97c1-4492-8885-7c2a1e65ae08' User entered '09 Sep 2020 18:53'	System	09 Sep 2020 23:53:17
	System	09 Sep 2020 23:53:17

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 7'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:43', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bc7cc0cc-9b3e-4555-95e8-1abd0b8a4481'	System	10 Sep 2020 23:44:00
User entered 'None (1)'	System	10 Sep 2020 23:44:00

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bc7cc0cc-9b3e-4555-95e8-1abd0b8a4481'	System	10 Sep 2020 23:44:00
User entered 'No (N)'	System	10 Sep 2020 23:44:00

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:49', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bc7cc0cc-9b3e-4555-95e8-1abd0b8a4481'	System	10 Sep 2020 23:44:00
User entered 'No (N)'	System	10 Sep 2020 23:44:00

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:51', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bc7cc0cc-9b3e-4555-95e8-1abd0b8a4481'	System	10 Sep 2020 23:44:00
User entered 'None (1)'	System	10 Sep 2020 23:44:00

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:54', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bc7cc0cc-9b3e-4555-95e8-1abd0b8a4481'	System	10 Sep 2020 23:44:00
User entered '10 Sep 2020 17:43'	System	10 Sep 2020 23:44:00

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:57:44', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '395be098-119f-4e59-b7d1-12f220d31c0a'	System	04 Sep 2020 16:58:24
User entered 'None (0)'	System	04 Sep 2020 16:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:57:50', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '395be098-119f-4e59-b7d1-12f220d31c0a'	System	04 Sep 2020 16:58:24
User entered 'None (0)'	System	04 Sep 2020 16:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:57:55', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '395be098-119f-4e59-b7d1-12f220d31c0a'	System	04 Sep 2020 16:58:24
User entered 'None (0)'	System	04 Sep 2020 16:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:58:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '395be098-119f-4e59-b7d1-12f220d31c0a'	System	04 Sep 2020 16:58:24
User entered 'None (0)'	System	04 Sep 2020 16:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:58:02', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '395be098-119f-4e59-b7d1-12f220d31c0a'	System	04 Sep 2020 16:58:24
User entered 'None (0)'	System	04 Sep 2020 16:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:58:05', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '395be098-119f-4e59-b7d1-12f220d31c0a'	System	04 Sep 2020 16:58:24
User entered 'None (0)'	System	04 Sep 2020 16:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:58:13', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '395be098-119f-4e59-b7d1-12f220d31c0a'	System	04 Sep 2020 16:58:24
User entered 'No (N)'	System	04 Sep 2020 16:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T11:58:21', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '395be098-119f-4e59-b7d1-12f220d31c0a'	System	04 Sep 2020 16:58:24
User entered '04 Sep 2020 11:58'	System	04 Sep 2020 16:58:24

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Sep 2020 11:57'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Sep 2020 14:27'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:31:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7754cf83-4815-46bb-a81f-65f3daaba9eb'	System	05 Sep 2020 00:31:50
User entered 'None (0)'	System	05 Sep 2020 00:31:50

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:31:22', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7754cf83-4815-46bb-a81f-65f3daaba9eb'	System	05 Sep 2020 00:31:50
User entered 'None (0)'	System	05 Sep 2020 00:31:50

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:31:27', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7754cf83-4815-46bb-a81f-65f3daaba9eb'	System	05 Sep 2020 00:31:50
User entered 'None (0)'	System	05 Sep 2020 00:31:50

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:31:30', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7754cf83-4815-46bb-a81f-65f3daaba9eb'	System	05 Sep 2020 00:31:50
User entered 'None (0)'	System	05 Sep 2020 00:31:50

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:31:32', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7754cf83-4815-46bb-a81f-65f3daaba9eb'	System	05 Sep 2020 00:31:50
User entered 'None (0)'	System	05 Sep 2020 00:31:50

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:31:35', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7754cf83-4815-46bb-a81f-65f3daaba9eb'	System	05 Sep 2020 00:31:50
User entered 'None (0)'	System	05 Sep 2020 00:31:50

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:31:40', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7754cf83-4815-46bb-a81f-65f3daaba9eb'	System	05 Sep 2020 00:31:50
User entered 'No (N)'	System	05 Sep 2020 00:31:50

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-04T19:31:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7754cf83-4815-46bb-a81f-65f3daaba9eb'	System	05 Sep 2020 00:31:50
User entered '04 Sep 2020 19:31'	System	05 Sep 2020 00:31:50

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Sep 2020 15:22'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 2'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:18', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ad7c09ec-8384-46c4-9d76-1696a3234911' User entered 'None (0)'	System	06 Sep 2020 02:18:47
	System	06 Sep 2020 02:18:47

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:21', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ad7c09ec-8384-46c4-9d76-1696a3234911'	System	06 Sep 2020 02:18:47
User entered 'No interference with activity (1)'	System	06 Sep 2020 02:18:47

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:25', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ad7c09ec-8384-46c4-9d76-1696a3234911'	System	06 Sep 2020 02:18:47
User entered 'No interference with activity (1)'	System	06 Sep 2020 02:18:47

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:29', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ad7c09ec-8384-46c4-9d76-1696a3234911'	System	06 Sep 2020 02:18:47
User entered 'No interference with activity (1)'	System	06 Sep 2020 02:18:47

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:32', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ad7c09ec-8384-46c4-9d76-1696a3234911'	System	06 Sep 2020 02:18:47
User entered 'None (0)'	System	06 Sep 2020 02:18:47

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:34', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ad7c09ec-8384-46c4-9d76-1696a3234911'	System	06 Sep 2020 02:18:47
User entered 'None (0)'	System	06 Sep 2020 02:18:47

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:40', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ad7c09ec-8384-46c4-9d76-1696a3234911'	System	06 Sep 2020 02:18:47
User entered 'No (N)'	System	06 Sep 2020 02:18:47

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-05T21:18:43', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ad7c09ec-8384-46c4-9d76-1696a3234911'	System	06 Sep 2020 02:18:47
User entered '05 Sep 2020 21:18'	System	06 Sep 2020 02:18:47

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 3'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:36', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cb02483-5161-4196-895a-d62ed3002e9c'	System	07 Sep 2020 01:09:57
User entered 'None (0)'	System	07 Sep 2020 01:09:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:38', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cb02483-5161-4196-895a-d62ed3002e9c'	System	07 Sep 2020 01:09:57
User entered 'None (0)'	System	07 Sep 2020 01:09:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:41', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cb02483-5161-4196-895a-d62ed3002e9c'	System	07 Sep 2020 01:09:57
User entered 'None (0)'	System	07 Sep 2020 01:09:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:43', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cb02483-5161-4196-895a-d62ed3002e9c' User entered 'None (0)'	System	07 Sep 2020 01:09:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:45', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cb02483-5161-4196-895a-d62ed3002e9c' User entered 'None (0)'	System	07 Sep 2020 01:09:57
	System	07 Sep 2020 01:09:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:47', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cb02483-5161-4196-895a-d62ed3002e9c'	System	07 Sep 2020 01:09:57
User entered 'None (0)'	System	07 Sep 2020 01:09:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:51', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cb02483-5161-4196-895a-d62ed3002e9c'	System	07 Sep 2020 01:09:57
User entered 'No (N)'	System	07 Sep 2020 01:09:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-06T20:09:55', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cb02483-5161-4196-895a-d62ed3002e9c'	System	07 Sep 2020 01:09:57
User entered '06 Sep 2020 20:09'	System	07 Sep 2020 01:09:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 4'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:47', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '08f598d8-4a59-4566-952c-fb2368cf7206'	System	07 Sep 2020 22:59:10
User entered 'None (0)'	System	07 Sep 2020 22:59:10

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:50', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '08f598d8-4a59-4566-952c-fb2368cf7206'	System	07 Sep 2020 22:59:10
User entered 'None (0)'	System	07 Sep 2020 22:59:10

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:52', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '08f598d8-4a59-4566-952c-fb2368cf7206'	System	07 Sep 2020 22:59:10
User entered 'None (0)'	System	07 Sep 2020 22:59:10

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:54', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '08f598d8-4a59-4566-952c-fb2368cf7206'	System	07 Sep 2020 22:59:10
User entered 'None (0)'	System	07 Sep 2020 22:59:10

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:57', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '08f598d8-4a59-4566-952c-fb2368cf7206'	System	07 Sep 2020 22:59:10
User entered 'None (0)'	System	07 Sep 2020 22:59:10

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:58:59', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '08f598d8-4a59-4566-952c-fb2368cf7206'	System	07 Sep 2020 22:59:10
User entered 'None (0)'	System	07 Sep 2020 22:59:10

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:59:03', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '08f598d8-4a59-4566-952c-fb2368cf7206'	System	07 Sep 2020 22:59:10
User entered 'No (N)'	System	07 Sep 2020 22:59:10

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-07T17:59:05', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '08f598d8-4a59-4566-952c-fb2368cf7206'	System	07 Sep 2020 22:59:10
User entered '07 Sep 2020 17:59'	System	07 Sep 2020 22:59:10

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 5'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:19', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f9f34a5a-f174-408f-a9d9-f3a213f8c220'	System	09 Sep 2020 03:22:41
User entered 'None (0)'	System	09 Sep 2020 03:22:41

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:22', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f9f34a5a-f174-408f-a9d9-f3a213f8c220'	System	09 Sep 2020 03:22:41
User entered 'None (0)'	System	09 Sep 2020 03:22:41

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:24', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f9f34a5a-f174-408f-a9d9-f3a213f8c220'	System	09 Sep 2020 03:22:41
User entered 'None (0)'	System	09 Sep 2020 03:22:41

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:25', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f9f34a5a-f174-408f-a9d9-f3a213f8c220'	System	09 Sep 2020 03:22:41
User entered 'None (0)'	System	09 Sep 2020 03:22:41

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:28', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f9f34a5a-f174-408f-a9d9-f3a213f8c220'	System	09 Sep 2020 03:22:41
User entered 'None (0)'	System	09 Sep 2020 03:22:41

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:30', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f9f34a5a-f174-408f-a9d9-f3a213f8c220'	System	09 Sep 2020 03:22:41
User entered 'None (0)'	System	09 Sep 2020 03:22:41

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:34', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f9f34a5a-f174-408f-a9d9-f3a213f8c220'	System	09 Sep 2020 03:22:41
User entered 'No (N)'	System	09 Sep 2020 03:22:41

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-08T22:22:36', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f9f34a5a-f174-408f-a9d9-f3a213f8c220'	System	09 Sep 2020 03:22:41
User entered '08 Sep 2020 22:22'	System	09 Sep 2020 03:22:41

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 6'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:52:39', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '2388c64c-3392-4099-8bf2-a580dcfdadcd' User entered 'None (0)'	System	09 Sep 2020 23:52:57
	System	09 Sep 2020 23:52:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:52:41', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '2388c64c-3392-4099-8bf2-a580dcfdadcd'	System	09 Sep 2020 23:52:57
User entered 'None (0)'	System	09 Sep 2020 23:52:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:52:43', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '2388c64c-3392-4099-8bf2-a580dcfdadcd' User entered 'None (0)'	System	09 Sep 2020 23:52:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:52:45', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '2388c64c-3392-4099-8bf2-a580dcfdadcd' User entered 'None (0)'	System	09 Sep 2020 23:52:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:52:48', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '2388c64c-3392-4099-8bf2-a580dcfdadcd' User entered 'None (0)'	System	09 Sep 2020 23:52:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:52:49', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '2388c64c-3392-4099-8bf2-a580dcfdadcd' User entered 'None (0)'	System	09 Sep 2020 23:52:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:52:52', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '2388c64c-3392-4099-8bf2-a580dcfdadcd' User entered 'No (N)'	System	09 Sep 2020 23:52:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-09T18:52:55', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '2388c64c-3392-4099-8bf2-a580dcfdadcd'	System	09 Sep 2020 23:52:57
User entered '09 Sep 2020 18:52'	System	09 Sep 2020 23:52:57

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 7'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:22', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c4b8401a-5a14-4e72-a089-1cce29c69f82'	System	10 Sep 2020 23:43:42
User entered 'None (0)'	System	10 Sep 2020 23:43:42

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:24', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c4b8401a-5a14-4e72-a089-1cce29c69f82'	System	10 Sep 2020 23:43:42
User entered 'None (0)'	System	10 Sep 2020 23:43:42

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:26', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c4b8401a-5a14-4e72-a089-1cce29c69f82'	System	10 Sep 2020 23:43:42
User entered 'None (0)'	System	10 Sep 2020 23:43:42

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:29', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c4b8401a-5a14-4e72-a089-1cce29c69f82'	System	10 Sep 2020 23:43:42
User entered 'None (0)'	System	10 Sep 2020 23:43:42

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:31', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c4b8401a-5a14-4e72-a089-1cce29c69f82'	System	10 Sep 2020 23:43:42
User entered 'None (0)'	System	10 Sep 2020 23:43:42

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:32', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c4b8401a-5a14-4e72-a089-1cce29c69f82'	System	10 Sep 2020 23:43:42
User entered 'None (0)'	System	10 Sep 2020 23:43:42

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:36', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c4b8401a-5a14-4e72-a089-1cce29c69f82'	System	10 Sep 2020 23:43:42
User entered 'No (N)'	System	10 Sep 2020 23:43:42

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-09-10T17:43:38', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c4b8401a-5a14-4e72-a089-1cce29c69f82'	System	10 Sep 2020 23:43:42
User entered '10 Sep 2020 17:43'	System	10 Sep 2020 23:43:42

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 16:41:26

US3862128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:25:56
User entered 'Yes (Y)'	Coni Cheesman (b) (4) (b) (4)	14 Sep 2020 20:16:01

US3862128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:25:56
User entered '11 Sep 2020'	Coni Cheesman (b) (4) (b) (4)	14 Sep 2020 20:16:01

US3862128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:25:56
User entered 'Contact Made (CONTACT MADE)'	Coni Cheesman (b) (4) (b) (4)	14 Sep 2020 20:16:01

US3862128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:25:56
User entered empty.	Coni Cheesman (b) (4) (b) (4)	14 Sep 2020 20:16:01

US3862128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:26:00
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 22:45:07

US3862128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User entered '1'	System	18 Sep 2020 22:45:07

US3862128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:26:43
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 22:45:20

US3862128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:26:43
User entered '18 Sep 2020'	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 22:45:20

US3862128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4)	14 Oct 2020 18:26:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 18:26:43
	Chanei Henry (b) (4)	18 Sep 2020 22:45:20
	(b) (4)	

US3862128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:26:43
User entered empty.	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 22:45:20

US3862128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:26:47
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	18 Sep 2020 22:45:25

US3862128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:47:56
User entered '1'	System	18 Sep 2020 22:45:25

US3862128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:27
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:27:30
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	25 Sep 2020 23:25:23

US3862128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:27
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:27:30
User entered '25 Sep 2020'	Carrie Kibler (b) (4) (b) (4)	25 Sep 2020 23:25:23

US3862128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:27
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:27:30
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4) (b) (4)	25 Sep 2020 23:25:23

US3862128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:27
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:27:30
User entered empty.	Carrie Kibler (b) (4) (b) (4)	25 Sep 2020 23:25:23

US3862128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:27
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:27:34
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	25 Sep 2020 23:25:27

US3862128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:42:27
User entered '1'	System	25 Sep 2020 23:25:27

US3862128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 18:08:13
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	02 Oct 2020 17:57:15

US3862128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	08 Dec 2020 18:08:13
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 17:57:31
User entered '01 Oct 2020'	Sandra Francisco (b) (4)	02 Oct 2020 17:57:15
	(b) (4)	

US3862128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[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 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:08:13
User entered 'Clinic (Clinic)'	Sandra Francisco (b) (4) (b) (4)	02 Oct 2020 17:57:15

US3862128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'VISIT2'	System	02 Oct 2020 17:57:15

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	08 Dec 2020 18:09:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 18:09:49
	Trent Davis (b) (4)	02 Oct 2020 22:06:50
	(b) (4)	

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:09:50
User entered '2 Oct 2020'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:09:54
User entered '10:26'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '2 Oct 2020 10:26'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:09:55
User entered '098.0' F	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:09:57
User entered 'Other (Other)'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:09:58
User entered 'temporal'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:01
User entered '069'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'bpm'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:03
User entered '016'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'breaths/min'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 18:10:07
User entered '133'	Trent Davis (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'mmHg'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:09
User entered '089'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'mmHg'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:43:35
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:43:35
User entered '2 Oct 2020'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:43:35
User closed query 'Per CDM Re-Query: Site response noted; however data has not been updated. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:05:11
Query 'Per CDM Re-Query: Site response noted; however data has not been updated. Please review and reconcile. Thank you.' answered with 'data corrected' (Site from DM).	Trent Davis (b) (4)	04 Nov 2020 19:00:49
User entered '13:15' reason for change: Data Entry Error	Trent Davis (b) (4)	04 Nov 2020 19:00:42
User opened query 'Per CDM Re-Query: Site response noted; however data has not been updated. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:58:37
User closed query 'Per CDM: The treatment time on the Exposure CRF is 12:45 and the Vital Signs Post Dose Time of Assessment is 13:14 which has 29 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:58:37
Query 'Per CDM: The treatment time on the Exposure CRF is 12:45 and the Vital Signs Post Dose Time of Assessment is 13:14 which has 29 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed.' answered with 'Data corrected.' (Site from DM).	Shetel Anassi (b) (4)	28 Oct 2020 21:02:40
User opened query 'Per CDM: The treatment time on the Exposure CRF is 12:45 and the Vital Signs Post Dose Time of Assessment is 13:14 which has 29 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:34:11

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:14'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '2 Oct 2020 13:15'	System	04 Nov 2020 19:00:42
User entered '2 Oct 2020 13:14'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:43:35
User entered '097.9' F	Trent Davis (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:43:35
User entered 'Other (Other)'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:43:35
User entered 'temporal'	Trent Davis (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:43:35
User entered '076'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'bpm'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:43:35
User entered '020'	Trent Davis (b) (4)	02 Oct 2020 22:06:50
	(b) (4)	

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'breaths/min'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:43:35
User entered '141'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'mmHg'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:43:35
User entered '087'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'mmHg'	System	02 Oct 2020 22:06:50

US3862128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	08 Dec 2020 18:09:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 17:57:25
	Sandra Francisco (b) (4)	
	(b) (4)	

US3862128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	08 Dec 2020 18:09:18
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 17:57:31
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 17:57:25
User entered '02 Oct 2020'	Sandra Francisco (b) (4)	02 Oct 2020 17:57:25
	(b) (4)	

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	08 Dec 2020 18:10:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 18:10:53
	Sandra Francisco (b) (4)	02 Oct 2020 17:57:06
	(b) (4)	

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:53
User entered empty.	Sandra Francisco (b) (4) (b) (4)	02 Oct 2020 17:57:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

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 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:53
User entered empty.	Sandra Francisco (b) (4) (b) (4)	02 Oct 2020 17:57:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 17:57:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:53
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 17:57:31
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	02 Oct 2020 17:57:31
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 17:57:15
User entered '02 Oct 2020'	Sandra Francisco (b) (4) (b) (4)	02 Oct 2020 17:57:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:53
User entered '12:45'	Sandra Francisco (b) (4) (b) (4)	02 Oct 2020 17:57:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '02 Oct 2020 12:45'	System	02 Oct 2020 17:57:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:10:53
User entered 'Right Arm (RIGHT ARM)'	Sandra Francisco (b) (4) (b) (4)	02 Oct 2020 17:57:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
DataPoint Verified.		08 Dec 2020 18:10:53
User entered 'ONCE'	System	02 Oct 2020 17:57:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:06:48

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 17:57:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:11:01
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:07:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:11:01
User entered '2 Oct 2020'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:07:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:11:01
User entered '11:30'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:07:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '2 Oct 2020 11:30'	System	02 Oct 2020 22:07:06

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:06:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:17:18
User entered '2 Oct 2020'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:07:23

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4)	02 Oct 2020 22:07:23

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 18:17:18
User entered 'No (N)'	Trent Davis (b) (4)	02 Oct 2020 22:07:23

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:17:18
User entered empty.	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:07:23

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:06:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered empty.	System	02 Oct 2020 22:07:23

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:07:23

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:17:18
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:07:23

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:17:18
User entered '11:09'	Trent Davis (b) (4) (b) (4)	02 Oct 2020 22:07:23

US3862128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:06:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '2 Oct 2020 11:09'	System	02 Oct 2020 22:07:23

US3862128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	08 Dec 2020 18:17:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 23:48:22
	Chanei Henry (b) (4)	
	(b) (4)	

US3862128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '1'	System	13 Oct 2020 23:48:22

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:16:55', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '62543915-91cd-4d88-a89b-85353da03b6a'	System	02 Oct 2020 18:17:18
User entered 'Yes (Y)'	System	02 Oct 2020 18:17:18

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:17:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '62543915-91cd-4d88-a89b-85353da03b6a' User entered '97.9'	System	02 Oct 2020 18:17:18
	System	02 Oct 2020 18:17:18

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:17:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '62543915-91cd-4d88-a89b-85353da03b6a'	System	02 Oct 2020 18:17:18
User entered 'No (N)'	System	02 Oct 2020 18:17:18

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:17:14', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '62543915-91cd-4d88-a89b-85353da03b6a'	System	02 Oct 2020 18:17:18
User entered '02 Oct 2020 13:17'	System	02 Oct 2020 18:17:18

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '02 Oct 2020 13:05'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '02 Oct 2020 15:35'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:04:28', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cc1a9a5-e818-4451-87f7-e3a473060079'	System	03 Oct 2020 01:04:49
User entered 'Yes (Y)'	System	03 Oct 2020 01:04:49

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:04:38', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cc1a9a5-e818-4451-87f7-e3a473060079' User entered '98.2'	System	03 Oct 2020 01:04:49
	System	03 Oct 2020 01:04:49

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:04:42', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cc1a9a5-e818-4451-87f7-e3a473060079'	System	03 Oct 2020 01:04:49
User entered 'No (N)'	System	03 Oct 2020 01:04:49

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:04:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6cc1a9a5-e818-4451-87f7-e3a473060079'	System	03 Oct 2020 01:04:49
User entered '02 Oct 2020 20:04'	System	03 Oct 2020 01:04:49

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '02 Oct 2020 16:30'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 2'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:31:29', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bd441323-0474-498d-8667-184b8f20fcb5'	System	03 Oct 2020 23:32:13
User entered 'Yes (Y)'	System	03 Oct 2020 23:32:13

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:31:36', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bd441323-0474-498d-8667-184b8f20fcb5' User entered '99.0'	System	03 Oct 2020 23:32:13
	System	03 Oct 2020 23:32:13

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:31:42', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bd441323-0474-498d-8667-184b8f20fcb5'	System	03 Oct 2020 23:32:13
User entered 'Yes (Y)'	System	03 Oct 2020 23:32:13

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmeds updated.' (Site from System).	(b) (4)	03 Nov 2020 14:04:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Shetel Anassi (b) (4)	28 Oct 2020 21:01:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bd441323-0474-498d-8667-184b8f20fcb5'	(b) (4)	
User entered '1'	System	03 Oct 2020 23:32:13
	System	03 Oct 2020 23:32:13
	System	03 Oct 2020 23:32:13

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bd441323-0474-498d-8667-184b8f20fcb5' User entered '0'	System	03 Oct 2020 23:32:13
	System	03 Oct 2020 23:32:13

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:11', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'bd441323-0474-498d-8667-184b8f20fcb5' User entered '03 Oct 2020 18:32'	System	03 Oct 2020 23:32:13
	System	03 Oct 2020 23:32:13

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 3'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T20:36:40', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5e127f26-12fe-4a8b-998b-54a30da8c944'	System	05 Oct 2020 01:36:55
User entered 'Yes (Y)'	System	05 Oct 2020 01:36:55

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T20:36:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5e127f26-12fe-4a8b-998b-54a30da8c944'	System	05 Oct 2020 01:36:55
User entered '97.7'	System	05 Oct 2020 01:36:55

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T20:36:50', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5e127f26-12fe-4a8b-998b-54a30da8c944'	System	05 Oct 2020 01:36:55
User entered 'No (N)'	System	05 Oct 2020 01:36:55

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T20:36:54', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5e127f26-12fe-4a8b-998b-54a30da8c944'	System	05 Oct 2020 01:36:55
User entered '04 Oct 2020 20:36'	System	05 Oct 2020 01:36:55

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 4'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:05', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '41372752-f8c4-47be-afcb-09247f289a27'	System	06 Oct 2020 03:17:22
User entered 'Yes (Y)'	System	06 Oct 2020 03:17:22

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:11', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '41372752-f8c4-47be-afcb-09247f289a27' User entered '97.2'	System	06 Oct 2020 03:17:22
	System	06 Oct 2020 03:17:22

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:14', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '41372752-f8c4-47be-afcb-09247f289a27'	System	06 Oct 2020 03:17:22
User entered 'No (N)'	System	06 Oct 2020 03:17:22

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:17', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '41372752-f8c4-47be-afcb-09247f289a27'	System	06 Oct 2020 03:17:22
User entered '05 Oct 2020 22:17'	System	06 Oct 2020 03:17:22

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 5'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:15:35', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b41bbda7-1529-41d3-9588-5142c84af485'	System	07 Oct 2020 01:15:55
User entered 'Yes (Y)'	System	07 Oct 2020 01:15:55

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:15:43', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b41bbda7-1529-41d3-9588-5142c84af485' User entered '97.5'	System	07 Oct 2020 01:15:55
	System	07 Oct 2020 01:15:55

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:15:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b41bbda7-1529-41d3-9588-5142c84af485'	System	07 Oct 2020 01:15:55
User entered 'No (N)'	System	07 Oct 2020 01:15:55

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:15:50', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b41bbda7-1529-41d3-9588-5142c84af485'	System	07 Oct 2020 01:15:55
User entered '06 Oct 2020 20:15'	System	07 Oct 2020 01:15:55

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 6'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:03:45', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '826914f2-7f43-41be-a69d-58daafb301b1'	System	08 Oct 2020 02:04:07
User entered 'Yes (Y)'	System	08 Oct 2020 02:04:07

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:03:52', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '826914f2-7f43-41be-a69d-58daafb301b1' User entered '97.7'	System	08 Oct 2020 02:04:07
	System	08 Oct 2020 02:04:07

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:03:56', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '826914f2-7f43-41be-a69d-58daafb301b1'	System	08 Oct 2020 02:04:07
User entered 'No (N)'	System	08 Oct 2020 02:04:07

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:04:04', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '826914f2-7f43-41be-a69d-58daafb301b1' User entered '07 Oct 2020 21:04'	System	08 Oct 2020 02:04:07
	System	08 Oct 2020 02:04:07

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 7'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:54', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f0e854ab-8616-4bce-af94-46d97c8e8bc4'	System	09 Oct 2020 03:16:12
User entered 'Yes (Y)'	System	09 Oct 2020 03:16:12

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:16:03', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f0e854ab-8616-4bce-af94-46d97c8e8bc4' User entered '97.0'	System	09 Oct 2020 03:16:12
	System	09 Oct 2020 03:16:12

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:16:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f0e854ab-8616-4bce-af94-46d97c8e8bc4'	System	09 Oct 2020 03:16:12
User entered 'No (N)'	System	09 Oct 2020 03:16:12

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:16:09', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f0e854ab-8616-4bce-af94-46d97c8e8bc4'	System	09 Oct 2020 03:16:12
User entered '08 Oct 2020 22:16'	System	09 Oct 2020 03:16:12

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:14:36', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'dbcfe5c5-d5a8-465f-8d2b-5a84976def1d'	System	02 Oct 2020 18:15:57
User entered 'None (1)'	System	02 Oct 2020 18:15:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:15:14', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'dbcfe5c5-d5a8-465f-8d2b-5a84976def1d'	System	02 Oct 2020 18:15:57
User entered 'No (N)'	System	02 Oct 2020 18:15:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:15:21', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'dbcfe5c5-d5a8-465f-8d2b-5a84976def1d'	System	02 Oct 2020 18:15:57
User entered 'Yes (Y)'	System	02 Oct 2020 18:15:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:15:37', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'dbcfe5c5-d5a8-465f-8d2b-5a84976def1d' User entered '1'	System	02 Oct 2020 18:15:57
	System	02 Oct 2020 18:15:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:15:41', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'dbcfe5c5-d5a8-465f-8d2b-5a84976def1d'	System	02 Oct 2020 18:15:57
User entered 'None (1)'	System	02 Oct 2020 18:15:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:15:54', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'dbcfe5c5-d5a8-465f-8d2b-5a84976def1d' User entered '02 Oct 2020 13:15'	System	02 Oct 2020 18:15:57
	System	02 Oct 2020 18:15:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '02 Oct 2020 13:05'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '02 Oct 2020 15:35'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b4a9096e-1967-4d0a-a8b6-f396d95ca523'	System	03 Oct 2020 01:09:03
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 01:09:03

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:05:22', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b4a9096e-1967-4d0a-a8b6-f396d95ca523'	System	03 Oct 2020 01:09:03
User entered 'Yes (Y)'	System	03 Oct 2020 01:09:03

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:08:43', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b4a9096e-1967-4d0a-a8b6-f396d95ca523' User entered '3'	System	03 Oct 2020 01:09:03
	System	03 Oct 2020 01:09:03

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:05:39', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b4a9096e-1967-4d0a-a8b6-f396d95ca523'	System	03 Oct 2020 01:09:03
User entered 'Yes (Y)'	System	03 Oct 2020 01:09:03

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:08:30', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b4a9096e-1967-4d0a-a8b6-f396d95ca523'	System	03 Oct 2020 01:09:03
User entered '18'	System	03 Oct 2020 01:09:03

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:06:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b4a9096e-1967-4d0a-a8b6-f396d95ca523'	System	03 Oct 2020 01:09:03
User entered 'None (1)'	System	03 Oct 2020 01:09:03

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:08:57', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b4a9096e-1967-4d0a-a8b6-f396d95ca523'	System	03 Oct 2020 01:09:03
User entered '02 Oct 2020 20:08'	System	03 Oct 2020 01:09:03

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '02 Oct 2020 16:30'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 2'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:21', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd95b2082-6c05-4819-acac-146437f6bad3'	System	03 Oct 2020 23:32:57
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 23:32:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:23', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd95b2082-6c05-4819-acac-146437f6bad3'	System	03 Oct 2020 23:32:57
User entered 'Yes (Y)'	System	03 Oct 2020 23:32:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:33', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd95b2082-6c05-4819-acac-146437f6bad3' User entered '28'	System	03 Oct 2020 23:32:57
	System	03 Oct 2020 23:32:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:37', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd95b2082-6c05-4819-acac-146437f6bad3'	System	03 Oct 2020 23:32:57
User entered 'Yes (Y)'	System	03 Oct 2020 23:32:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:41', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd95b2082-6c05-4819-acac-146437f6bad3' User entered '40'	System	03 Oct 2020 23:32:57
	System	03 Oct 2020 23:32:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd95b2082-6c05-4819-acac-146437f6bad3'	System	03 Oct 2020 23:32:57
User entered 'None (1)'	System	03 Oct 2020 23:32:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:32:53', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd95b2082-6c05-4819-acac-146437f6bad3' User entered '03 Oct 2020 18:32'	System	03 Oct 2020 23:32:57
	System	03 Oct 2020 23:32:57

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 3'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:45:08', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0ea3b4f9-f369-4efe-81a9-6cde07f80922'	System	04 Oct 2020 23:45:59
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 23:45:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:45:12', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0ea3b4f9-f369-4efe-81a9-6cde07f80922'	System	04 Oct 2020 23:45:59
User entered 'Yes (Y)'	System	04 Oct 2020 23:45:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:45:20', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0ea3b4f9-f369-4efe-81a9-6cde07f80922'	System	04 Oct 2020 23:45:59
User entered '75'	System	04 Oct 2020 23:45:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:45:24', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0ea3b4f9-f369-4efe-81a9-6cde07f80922'	System	04 Oct 2020 23:45:59
User entered 'Yes (Y)'	System	04 Oct 2020 23:45:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:45:38', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0ea3b4f9-f369-4efe-81a9-6cde07f80922'	System	04 Oct 2020 23:45:59
User entered '34'	System	04 Oct 2020 23:45:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:45:41', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0ea3b4f9-f369-4efe-81a9-6cde07f80922'	System	04 Oct 2020 23:45:59
User entered 'None (1)'	System	04 Oct 2020 23:45:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:45:55', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0ea3b4f9-f369-4efe-81a9-6cde07f80922'	System	04 Oct 2020 23:45:59
User entered '04 Oct 2020 18:45'	System	04 Oct 2020 23:45:59

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 4'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:19:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f232d1a7-657e-457c-9817-4557209ce158'	System	06 Oct 2020 03:19:32
User entered 'None (1)'	System	06 Oct 2020 03:19:32

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:19:09', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f232d1a7-657e-457c-9817-4557209ce158'	System	06 Oct 2020 03:19:32
User entered 'Yes (Y)'	System	06 Oct 2020 03:19:32

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:19:15', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f232d1a7-657e-457c-9817-4557209ce158'	System	06 Oct 2020 03:19:32
User entered '60'	System	06 Oct 2020 03:19:32

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:19:18', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f232d1a7-657e-457c-9817-4557209ce158'	System	06 Oct 2020 03:19:32
User entered 'No (N)'	System	06 Oct 2020 03:19:32

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:19:21', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f232d1a7-657e-457c-9817-4557209ce158'	System	06 Oct 2020 03:19:32
User entered 'None (1)'	System	06 Oct 2020 03:19:32

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:19:28', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f232d1a7-657e-457c-9817-4557209ce158'	System	06 Oct 2020 03:19:32
User entered '05 Oct 2020 22:19'	System	06 Oct 2020 03:19:32

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 5'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:18', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a881ee65-ccd1-48fc-9683-3945dbd99405'	System	07 Oct 2020 01:03:48
User entered 'None (1)'	System	07 Oct 2020 01:03:48

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:21', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a881ee65-ccd1-48fc-9683-3945dbd99405'	System	07 Oct 2020 01:03:48
User entered 'Yes (Y)'	System	07 Oct 2020 01:03:48

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:28', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a881ee65-ccd1-48fc-9683-3945dbd99405'	System	07 Oct 2020 01:03:48
User entered '52'	System	07 Oct 2020 01:03:48

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:31', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a881ee65-ccd1-48fc-9683-3945dbd99405'	System	07 Oct 2020 01:03:48
User entered 'No (N)'	System	07 Oct 2020 01:03:48

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:34', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a881ee65-ccd1-48fc-9683-3945dbd99405'	System	07 Oct 2020 01:03:48
User entered 'None (1)'	System	07 Oct 2020 01:03:48

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'a881ee65-ccd1-48fc-9683-3945dbd99405'	System	07 Oct 2020 01:03:48
User entered '06 Oct 2020 20:03'	System	07 Oct 2020 01:03:48

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 6'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:04:56', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8598ba74-a486-4f76-984b-46680e9b4380'	System	08 Oct 2020 02:05:22
User entered 'None (1)'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:04:58', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8598ba74-a486-4f76-984b-46680e9b4380'	System	08 Oct 2020 02:05:22
User entered 'Yes (Y)'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:05:03', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8598ba74-a486-4f76-984b-46680e9b4380' User entered '45'	System	08 Oct 2020 02:05:22
	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:05:08', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8598ba74-a486-4f76-984b-46680e9b4380'	System	08 Oct 2020 02:05:22
User entered 'No (N)'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:05:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8598ba74-a486-4f76-984b-46680e9b4380'	System	08 Oct 2020 02:05:22
User entered 'None (1)'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:05:19', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8598ba74-a486-4f76-984b-46680e9b4380' User entered '07 Oct 2020 21:05'	System	08 Oct 2020 02:05:22
	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 7'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:05', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '462340ae-c8ab-4b22-ac18-8f310bf24b51'	System	09 Oct 2020 03:15:26
User entered 'None (1)'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:07', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '462340ae-c8ab-4b22-ac18-8f310bf24b51'	System	09 Oct 2020 03:15:26
User entered 'Yes (Y)'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:15', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '462340ae-c8ab-4b22-ac18-8f310bf24b51' User entered '45'	System	09 Oct 2020 03:15:26
	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:18', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '462340ae-c8ab-4b22-ac18-8f310bf24b51'	System	09 Oct 2020 03:15:26
User entered 'No (N)'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:20', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '462340ae-c8ab-4b22-ac18-8f310bf24b51'	System	09 Oct 2020 03:15:26
User entered 'None (1)'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:23', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '462340ae-c8ab-4b22-ac18-8f310bf24b51'	System	09 Oct 2020 03:15:26
User entered '08 Oct 2020 22:15'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:16:07', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5d419368-8525-48c8-ad62-ecaab7046355'	System	02 Oct 2020 18:16:48
User entered 'None (0)'	System	02 Oct 2020 18:16:48

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:16:09', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5d419368-8525-48c8-ad62-ecaab7046355'	System	02 Oct 2020 18:16:48
User entered 'None (0)'	System	02 Oct 2020 18:16:48

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:16:12', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5d419368-8525-48c8-ad62-ecaab7046355'	System	02 Oct 2020 18:16:48
User entered 'None (0)'	System	02 Oct 2020 18:16:48

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:16:26', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5d419368-8525-48c8-ad62-ecaab7046355'	System	02 Oct 2020 18:16:48
User entered 'None (0)'	System	02 Oct 2020 18:16:48

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:16:30', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5d419368-8525-48c8-ad62-ecaab7046355'	System	02 Oct 2020 18:16:48
User entered 'None (0)'	System	02 Oct 2020 18:16:48

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:16:35', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5d419368-8525-48c8-ad62-ecaab7046355'	System	02 Oct 2020 18:16:48
User entered 'None (0)'	System	02 Oct 2020 18:16:48

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:16:39', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5d419368-8525-48c8-ad62-ecaab7046355'	System	02 Oct 2020 18:16:48
User entered 'No (N)'	System	02 Oct 2020 18:16:48

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T13:16:44', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5d419368-8525-48c8-ad62-ecaab7046355'	System	02 Oct 2020 18:16:48
User entered '02 Oct 2020 13:16'	System	02 Oct 2020 18:16:48

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '02 Oct 2020 13:05'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '02 Oct 2020 15:35'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:09:02', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd3d8fd91-6dd1-4c6e-a982-c23f68544b8c'	System	03 Oct 2020 01:09:28
User entered 'None (0)'	System	03 Oct 2020 01:09:28

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:09:05', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd3d8fd91-6dd1-4c6e-a982-c23f68544b8c'	System	03 Oct 2020 01:09:28
User entered 'None (0)'	System	03 Oct 2020 01:09:28

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:09:07', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd3d8fd91-6dd1-4c6e-a982-c23f68544b8c'	System	03 Oct 2020 01:09:28
User entered 'None (0)'	System	03 Oct 2020 01:09:28

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:09:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd3d8fd91-6dd1-4c6e-a982-c23f68544b8c'	System	03 Oct 2020 01:09:28
User entered 'None (0)'	System	03 Oct 2020 01:09:28

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:09:12', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd3d8fd91-6dd1-4c6e-a982-c23f68544b8c'	System	03 Oct 2020 01:09:28
User entered 'None (0)'	System	03 Oct 2020 01:09:28

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:09:14', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd3d8fd91-6dd1-4c6e-a982-c23f68544b8c'	System	03 Oct 2020 01:09:28
User entered 'None (0)'	System	03 Oct 2020 01:09:28

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:09:20', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd3d8fd91-6dd1-4c6e-a982-c23f68544b8c'	System	03 Oct 2020 01:09:28
User entered 'No (N)'	System	03 Oct 2020 01:09:28

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-02T20:09:25', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'd3d8fd91-6dd1-4c6e-a982-c23f68544b8c'	System	03 Oct 2020 01:09:28
User entered '02 Oct 2020 20:09'	System	03 Oct 2020 01:09:28

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '02 Oct 2020 16:30'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 2'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:33:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '36e69471-e820-4b27-8152-5ccfac1ec434'	System	03 Oct 2020 23:33:56
User entered 'No interference with activity (1)'	System	03 Oct 2020 23:33:56

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:33:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '36e69471-e820-4b27-8152-5ccfac1ec434'	System	03 Oct 2020 23:33:56
User entered 'Some interference with activity (2)'	System	03 Oct 2020 23:33:56

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:33:14', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '36e69471-e820-4b27-8152-5ccfac1ec434'	System	03 Oct 2020 23:33:56
User entered 'Some interference with activity (2)'	System	03 Oct 2020 23:33:56

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:33:18', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '36e69471-e820-4b27-8152-5ccfac1ec434'	System	03 Oct 2020 23:33:56
User entered 'Some interference with activity (2)'	System	03 Oct 2020 23:33:56

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:33:28', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '36e69471-e820-4b27-8152-5ccfac1ec434'	System	03 Oct 2020 23:33:56
User entered 'None (0)'	System	03 Oct 2020 23:33:56

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:33:39', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '36e69471-e820-4b27-8152-5ccfac1ec434'	System	03 Oct 2020 23:33:56
User entered 'Some interference with activity not requiring medical attention (2)'	System	03 Oct 2020 23:33:56

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:33:45', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '36e69471-e820-4b27-8152-5ccfac1ec434'	System	03 Oct 2020 23:33:56
User entered 'No (N)'	System	03 Oct 2020 23:33:56

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-03T18:33:50', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '36e69471-e820-4b27-8152-5ccfac1ec434'	System	03 Oct 2020 23:33:56
User entered '03 Oct 2020 18:33'	System	03 Oct 2020 23:33:56

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 3'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:46:01', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '64f98833-5fe5-4757-ae13-9479025ce2c1'	System	04 Oct 2020 23:46:29
User entered 'None (0)'	System	04 Oct 2020 23:46:29

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:46:04', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '64f98833-5fe5-4757-ae13-9479025ce2c1'	System	04 Oct 2020 23:46:29
User entered 'None (0)'	System	04 Oct 2020 23:46:29

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:46:09', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '64f98833-5fe5-4757-ae13-9479025ce2c1'	System	04 Oct 2020 23:46:29
User entered 'None (0)'	System	04 Oct 2020 23:46:29

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:46:12', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '64f98833-5fe5-4757-ae13-9479025ce2c1'	System	04 Oct 2020 23:46:29
User entered 'None (0)'	System	04 Oct 2020 23:46:29

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:46:14', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '64f98833-5fe5-4757-ae13-9479025ce2c1' User entered 'None (0)'	System	04 Oct 2020 23:46:29
	System	04 Oct 2020 23:46:29

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:46:18', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '64f98833-5fe5-4757-ae13-9479025ce2c1'	System	04 Oct 2020 23:46:29
User entered 'None (0)'	System	04 Oct 2020 23:46:29

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:46:22', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '64f98833-5fe5-4757-ae13-9479025ce2c1'	System	04 Oct 2020 23:46:29
User entered 'No (N)'	System	04 Oct 2020 23:46:29

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-04T18:46:25', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '64f98833-5fe5-4757-ae13-9479025ce2c1'	System	04 Oct 2020 23:46:29
User entered '04 Oct 2020 18:46'	System	04 Oct 2020 23:46:29

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 4'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:22', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ddf3b210-25cd-4cb1-9f85-d7ec67a6aeb0'	System	06 Oct 2020 03:17:42
User entered 'None (0)'	System	06 Oct 2020 03:17:42

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:24', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ddf3b210-25cd-4cb1-9f85-d7ec67a6aeb0'	System	06 Oct 2020 03:17:42
User entered 'None (0)'	System	06 Oct 2020 03:17:42

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:26', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ddf3b210-25cd-4cb1-9f85-d7ec67a6aeb0'	System	06 Oct 2020 03:17:42
User entered 'None (0)'	System	06 Oct 2020 03:17:42

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:28', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ddf3b210-25cd-4cb1-9f85-d7ec67a6aeb0'	System	06 Oct 2020 03:17:42
User entered 'None (0)'	System	06 Oct 2020 03:17:42

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:30', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ddf3b210-25cd-4cb1-9f85-d7ec67a6aeb0'	System	06 Oct 2020 03:17:42
User entered 'None (0)'	System	06 Oct 2020 03:17:42

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:32', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ddf3b210-25cd-4cb1-9f85-d7ec67a6aeb0'	System	06 Oct 2020 03:17:42
User entered 'None (0)'	System	06 Oct 2020 03:17:42

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:36', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ddf3b210-25cd-4cb1-9f85-d7ec67a6aeb0'	System	06 Oct 2020 03:17:42
User entered 'No (N)'	System	06 Oct 2020 03:17:42

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-05T22:17:39', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ddf3b210-25cd-4cb1-9f85-d7ec67a6aeb0' User entered '05 Oct 2020 22:17'	System	06 Oct 2020 03:17:42
	System	06 Oct 2020 03:17:42

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 5'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:50', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0365dbec-c0d9-49b5-bc75-c42d563faed9'	System	07 Oct 2020 01:04:13
User entered 'None (0)'	System	07 Oct 2020 01:04:13

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:53', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0365dbec-c0d9-49b5-bc75-c42d563faed9'	System	07 Oct 2020 01:04:13
User entered 'None (0)'	System	07 Oct 2020 01:04:13

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:55', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0365dbec-c0d9-49b5-bc75-c42d563faed9'	System	07 Oct 2020 01:04:13
User entered 'None (0)'	System	07 Oct 2020 01:04:13

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:56', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0365dbec-c0d9-49b5-bc75-c42d563faed9' User entered 'None (0)'	System	07 Oct 2020 01:04:13
	System	07 Oct 2020 01:04:13

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:03:58', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0365dbec-c0d9-49b5-bc75-c42d563faed9' User entered 'None (0)'	System	07 Oct 2020 01:04:13
	System	07 Oct 2020 01:04:13

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:04:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0365dbec-c0d9-49b5-bc75-c42d563faed9'	System	07 Oct 2020 01:04:13
User entered 'None (0)'	System	07 Oct 2020 01:04:13

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:04:04', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0365dbec-c0d9-49b5-bc75-c42d563faed9'	System	07 Oct 2020 01:04:13
User entered 'No (N)'	System	07 Oct 2020 01:04:13

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-06T20:04:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '0365dbec-c0d9-49b5-bc75-c42d563faed9' User entered '06 Oct 2020 20:04'	System	07 Oct 2020 01:04:13
	System	07 Oct 2020 01:04:13

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 6'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:02:51', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b0ada5f8-af0b-4a0e-82ad-7eadb6a8d55a'	System	08 Oct 2020 02:03:10
User entered 'None (0)'	System	08 Oct 2020 02:03:10

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:02:53', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b0ada5f8-af0b-4a0e-82ad-7eadb6a8d55a'	System	08 Oct 2020 02:03:10
User entered 'None (0)'	System	08 Oct 2020 02:03:10

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:02:55', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b0ada5f8-af0b-4a0e-82ad-7eadb6a8d55a'	System	08 Oct 2020 02:03:10
User entered 'None (0)'	System	08 Oct 2020 02:03:10

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:02:58', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b0ada5f8-af0b-4a0e-82ad-7eadb6a8d55a'	System	08 Oct 2020 02:03:10
User entered 'None (0)'	System	08 Oct 2020 02:03:10

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:03:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b0ada5f8-af0b-4a0e-82ad-7eadb6a8d55a'	System	08 Oct 2020 02:03:10
User entered 'None (0)'	System	08 Oct 2020 02:03:10

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:03:01', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b0ada5f8-af0b-4a0e-82ad-7eadb6a8d55a'	System	08 Oct 2020 02:03:10
User entered 'None (0)'	System	08 Oct 2020 02:03:10

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:03:04', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b0ada5f8-af0b-4a0e-82ad-7eadb6a8d55a'	System	08 Oct 2020 02:03:10
User entered 'No (N)'	System	08 Oct 2020 02:03:10

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-07T21:03:07', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'b0ada5f8-af0b-4a0e-82ad-7eadb6a8d55a'	System	08 Oct 2020 02:03:10
User entered '07 Oct 2020 21:03'	System	08 Oct 2020 02:03:10

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	02 Oct 2020 17:57:06
User entered 'Day 7'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:27', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8ec541b0-c830-457c-ab23-bc48bbb1986c'	System	09 Oct 2020 03:15:51
User entered 'None (0)'	System	09 Oct 2020 03:15:51

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:29', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8ec541b0-c830-457c-ab23-bc48bbb1986c' User entered 'None (0)'	System	09 Oct 2020 03:15:51
	System	09 Oct 2020 03:15:51

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:31', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8ec541b0-c830-457c-ab23-bc48bbb1986c'	System	09 Oct 2020 03:15:51
User entered 'None (0)'	System	09 Oct 2020 03:15:51

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:32', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8ec541b0-c830-457c-ab23-bc48bbb1986c' User entered 'None (0)'	System	09 Oct 2020 03:15:51
	System	09 Oct 2020 03:15:51

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:34', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8ec541b0-c830-457c-ab23-bc48bbb1986c'	System	09 Oct 2020 03:15:51
User entered 'None (0)'	System	09 Oct 2020 03:15:51

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:36', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8ec541b0-c830-457c-ab23-bc48bbb1986c'	System	09 Oct 2020 03:15:51
User entered 'None (0)'	System	09 Oct 2020 03:15:51

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:41', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8ec541b0-c830-457c-ab23-bc48bbb1986c'	System	09 Oct 2020 03:15:51
User entered 'No (N)'	System	09 Oct 2020 03:15:51

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-08T22:15:47', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8ec541b0-c830-457c-ab23-bc48bbb1986c'	System	09 Oct 2020 03:15:51
User entered '08 Oct 2020 22:15'	System	09 Oct 2020 03:15:51

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:57:06

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	08 Oct 2020 02:05:22
User entered 'Day 8'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-09T21:41:36', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '878735d6-1786-483c-a997-6f3d8a377b6d'	System	10 Oct 2020 02:41:56
User entered 'Yes (Y)'	System	10 Oct 2020 02:41:56

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-09T21:41:47', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '878735d6-1786-483c-a997-6f3d8a377b6d' User entered '35'	System	10 Oct 2020 02:41:56
	System	10 Oct 2020 02:41:56

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-09T21:41:52', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '878735d6-1786-483c-a997-6f3d8a377b6d' User entered '09 Oct 2020 21:41'	System	10 Oct 2020 02:41:56
	System	10 Oct 2020 02:41:56

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	09 Oct 2020 03:15:26
User entered 'Day 9'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-10T22:10:07', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'dec6da87-61dd-4bca-84c1-72c742c3c8dd'	System	11 Oct 2020 03:10:21
User entered 'Yes (Y)'	System	11 Oct 2020 03:10:21

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-10T22:10:15', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'dec6da87-61dd-4bca-84c1-72c742c3c8dd'	System	11 Oct 2020 03:10:21
User entered '30'	System	11 Oct 2020 03:10:21

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-10T22:10:19', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'dec6da87-61dd-4bca-84c1-72c742c3c8dd'	System	11 Oct 2020 03:10:21
User entered '10 Oct 2020 22:10'	System	11 Oct 2020 03:10:21

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	10 Oct 2020 02:41:56
User entered 'Day 10'	System	10 Oct 2020 02:41:56

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 10 Jun 2021 10:06:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-11T12:01:34', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c1d917a1-a4c0-42fd-88d0-807b3be4b8df'	System	11 Oct 2020 17:01:46
User entered 'No (N)'	System	11 Oct 2020 17:01:46

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 10 Jun 2021 10:06:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-11T12:01:37', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c1d917a1-a4c0-42fd-88d0-807b3be4b8df'	System	11 Oct 2020 17:01:46
User entered '11 Oct 2020 12:01'	System	11 Oct 2020 17:01:46

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 02:41:56

US3862128

Folder: Diary Dose 2 (1)

Form: Redness_Day(10)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 02:41:56

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	08 Oct 2020 02:05:22
User entered 'Day 8'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-09T21:41:58', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f0bd50e2-19a5-4b60-97f7-2d6753eb49ec'	System	10 Oct 2020 02:42:04
User entered 'No (N)'	System	10 Oct 2020 02:42:04

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-09T21:42:01', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'f0bd50e2-19a5-4b60-97f7-2d6753eb49ec'	System	10 Oct 2020 02:42:04
User entered '09 Oct 2020 21:42'	System	10 Oct 2020 02:42:04

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 02:05:22

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	09 Oct 2020 03:15:26
User entered 'Day 9'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-10T22:09:57', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c13adf8f-38de-469d-8f46-1608ae99c54c'	System	11 Oct 2020 03:10:04
User entered 'No (N)'	System	11 Oct 2020 03:10:04

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-10T22:10:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'c13adf8f-38de-469d-8f46-1608ae99c54c'	System	11 Oct 2020 03:10:04
User entered '10 Oct 2020 22:10'	System	11 Oct 2020 03:10:04

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:15:26

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
Data entry locked.	System	10 Oct 2020 02:41:56
User entered 'Day 10'	System	10 Oct 2020 02:41:56

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:06:48

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)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-11T12:01:28', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ee9d2c41-6cae-4c7b-9e73-8cf8a9328138'	System	11 Oct 2020 17:01:40
User entered 'No (N)'	System	11 Oct 2020 17:01:40

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:06:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-10-11T12:01:31', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ee9d2c41-6cae-4c7b-9e73-8cf8a9328138'	System	11 Oct 2020 17:01:40
User entered '11 Oct 2020 12:01'	System	11 Oct 2020 17:01:40

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:06:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 02:41:56

US3862128

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 10:06:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:52
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 02:41:56

US3862128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:49:50
User entered 'Yes (Y)'	Chanei Henry (b) (4)	13 Oct 2020 23:48:34

US3862128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:49:50
User entered '9 Oct 2020'	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:48:34

US3862128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:49:50
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:48:34

US3862128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:49:50
User entered empty.	Chanei Henry (b) (4)	13 Oct 2020 23:48:34
	(b) (4)	

US3862128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:49:57
User entered 'Yes (Y)'	Chanei Henry (b) (4)	13 Oct 2020 23:48:45
	(b) (4)	

US3862128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '1'	System	13 Oct 2020 23:48:45

US3862128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:54:55
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	19 Oct 2020 19:40:32

US3862128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:54:55
User entered '19 Oct 2020'	Carrie Kibler (b) (4)	19 Oct 2020 19:40:32
	(b) (4)	

US3862128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:54:55
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4) (b) (4)	19 Oct 2020 19:40:32

US3862128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:54:55
User entered empty.	Carrie Kibler (b) (4) (b) (4)	19 Oct 2020 19:40:32

US3862128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:54:58
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	19 Oct 2020 19:40:47

US3862128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '1'	System	19 Oct 2020 19:40:47

US3862128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	19 Jan 2021 20:57:32
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	17 Dec 2020 19:51:33
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	17 Dec 2020 19:48:17
User entered 'No (N)'	Shetel Anassi (b) (4)	17 Dec 2020 19:48:17

US3862128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:57:32
User entered empty.	Shetel Anassi (b) (4)	17 Dec 2020 19:48:17

US3862128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:57:32
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	17 Dec 2020 19:51:33
User entered 'Contact Not Made (CONTACT NOT MADE)'	Shetel Anassi (b) (4)	17 Dec 2020 19:48:17

US3862128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 19 Jan 2021 20:57:32
User entered 'No attempt made'	Shetel Anassi (b) (4)	17 Dec 2020 19:48:17
	(b) (4)	

US3862128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:57:35
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	30 Nov 2020 18:24:44

US3862128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '1'	System	30 Nov 2020 18:24:44

US3862128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	19 Jan 2021 21:05:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Jan 2021 21:05:22
	Shetel Anassi (b) (4)	17 Dec 2020 22:10:56
	(b) (4)	

US3862128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:05:22
User entered empty.	Shetel Anassi (b) (4)	17 Dec 2020 22:10:56
	(b) (4)	

US3862128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[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 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	19 Jan 2021 21:05:22
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 22:10:56
	Shetel Anassi (b) (4)	
	(b) (4)	

US3862128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered 'VISIT3'	System	17 Dec 2020 22:10:56

US3862128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:46:47
DataPoint Verified.	(b) (4)	19 Jan 2021 21:05:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 21:05:51
	Chanei Henry (b) (4)	30 Nov 2020 18:24:52
	(b) (4)	

US3862128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '1'	System	30 Nov 2020 18:24:52

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 64'	System	04 Sep 2020 16:41:26

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Have you been exposed to someone with 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)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Please 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)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Fever (Temperature $\geq$ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Please 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)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Please 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)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25
Data entry locked.	System	04 Sep 2020 16:41:26
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 16:41:26

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:52:25
Data entry locked.	System	04 Sep 2020 16:41:26
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 71'	System	04 Sep 2020 16:41:26

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-11-11T07:19:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '21c1c64e-ae45-4628-92a2-35543ddd2e0f'	System	11 Nov 2020 13:20:33
User entered 'No (N)'	System	11 Nov 2020 13:20:33

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Have you been exposed to someone with 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)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-11-11T07:20:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '21c1c64e-ae45-4628-92a2-35543ddd2e0f'	System	11 Nov 2020 13:20:33
User entered 'Yes (Y)'	System	11 Nov 2020 13:20:33

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Please 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)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-11-11T07:20:14', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '21c1c64e-ae45-4628-92a2-35543ddd2e0f'	System	11 Nov 2020 13:20:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 13:20:33

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-11-11T07:20:20', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '21c1c64e-ae45-4628-92a2-35543ddd2e0f'	System	11 Nov 2020 13:20:33
User entered '11 Nov 2020 07:20:20'	System	11 Nov 2020 13:20:33

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	04 Sep 2020 16:41:26
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 16:41:26

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	04 Sep 2020 16:41:26
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	04 Sep 2020 16:41:26
User entered 'Day 78'	System	04 Sep 2020 16:41:26

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-11-18T14:41:14', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '34bb5a6a-772f-4248-90e1-9ccaa40c347d'	System	18 Nov 2020 20:41:38
User entered 'No (N)'	System	18 Nov 2020 20:41:38

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-11-18T14:41:24', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '34bb5a6a-772f-4248-90e1-9ccaa40c347d'	System	18 Nov 2020 20:41:38
User entered 'No (N)'	System	18 Nov 2020 20:41:38

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-11-18T14:41:33', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '34bb5a6a-772f-4248-90e1-9ccaa40c347d' User entered '18 Nov 2020 14:41:33'	System	18 Nov 2020 20:41:38
	System	18 Nov 2020 20:41:38

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	04 Sep 2020 16:41:26
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 16:41:26

US3862128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:54
Data entry locked.	System	04 Sep 2020 16:41:26
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 16:41:26

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2020-11-29T12:06:44', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7aa66169-06bb-46a4-9792-3e4bad554fd9'	System	29 Nov 2020 18:07:03
User entered 'No (N)'	System	29 Nov 2020 18:07:03

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2020-11-29T12:06:49', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7aa66169-06bb-46a4-9792-3e4bad554fd9'	System	29 Nov 2020 18:07:03
User entered 'No (N)'	System	29 Nov 2020 18:07:03

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-11-29T12:06:57', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7aa66169-06bb-46a4-9792-3e4bad554fd9' User entered '29 Nov 2020 12:06:57'	System	29 Nov 2020 18:07:03
	System	29 Nov 2020 18:07:03

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2020-12-06T09:16:51', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8a8e422d-7114-4ed5-b653-caf70449d391'	System	06 Dec 2020 15:17:04
User entered 'No (N)'	System	06 Dec 2020 15:17:04

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2020-12-06T09:16:58', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8a8e422d-7114-4ed5-b653-caf70449d391'	System	06 Dec 2020 15:17:04
User entered 'No (N)'	System	06 Dec 2020 15:17:04

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-12-06T09:17:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '8a8e422d-7114-4ed5-b653-caf70449d391' User entered '06 Dec 2020 09:17:00'	System	06 Dec 2020 15:17:04
	System	06 Dec 2020 15:17:04

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2020-12-13T10:23:30', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '94beb366-1885-485b-9dff-8592c7cb7a5e'	System	13 Dec 2020 16:23:47
User entered 'No (N)'	System	13 Dec 2020 16:23:47

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2020-12-13T10:23:38', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '94beb366-1885-485b-9dff-8592c7cb7a5e'	System	13 Dec 2020 16:23:47
User entered 'No (N)'	System	13 Dec 2020 16:23:47

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-12-13T10:23:41', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '94beb366-1885-485b-9dff-8592c7cb7a5e'	System	13 Dec 2020 16:23:47
User entered '13 Dec 2020 10:23:41'	System	13 Dec 2020 16:23:47

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2020-12-22T12:43:31', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '403e2c71-8675-473c-a57b-84e919a593da'	System	22 Dec 2020 18:43:40
User entered 'No (N)'	System	22 Dec 2020 18:43:40

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2020-12-22T12:43:35', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '403e2c71-8675-473c-a57b-84e919a593da'	System	22 Dec 2020 18:43:40
User entered 'No (N)'	System	22 Dec 2020 18:43:40

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-12-22T12:43:38', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '403e2c71-8675-473c-a57b-84e919a593da' User entered '22 Dec 2020 12:43:38'	System	22 Dec 2020 18:43:40
	System	22 Dec 2020 18:43:40

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2020-12-29T13:42:51', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '76a129f8-d37a-4e5b-8978-f520398cb1b2'	System	29 Dec 2020 19:43:07
User entered 'No (N)'	System	29 Dec 2020 19:43:07

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2020-12-29T13:43:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '76a129f8-d37a-4e5b-8978-f520398cb1b2'	System	29 Dec 2020 19:43:07
User entered 'No (N)'	System	29 Dec 2020 19:43:07

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2020-12-29T13:43:03', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '76a129f8-d37a-4e5b-8978-f520398cb1b2' User entered '29 Dec 2020 13:43:03'	System	29 Dec 2020 19:43:07
	System	29 Dec 2020 19:43:07

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-01-03T07:19:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '56e42b66-c3ed-479f-b747-5930b0fb9bb7'	System	03 Jan 2021 13:19:12
User entered 'No (N)'	System	03 Jan 2021 13:19:12

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-01-03T07:19:04', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '56e42b66-c3ed-479f-b747-5930b0fb9bb7'	System	03 Jan 2021 13:19:12
User entered 'No (N)'	System	03 Jan 2021 13:19:12

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-01-03T07:19:09', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '56e42b66-c3ed-479f-b747-5930b0fb9bb7'	System	03 Jan 2021 13:19:12
User entered '03 Jan 2021 07:19:09'	System	03 Jan 2021 13:19:12

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-01-10T07:38:57', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7c057e69-36ac-475d-8f30-e850bbac5820'	System	10 Jan 2021 13:39:05
User entered 'No (N)'	System	10 Jan 2021 13:39:05

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-01-10T07:38:59', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7c057e69-36ac-475d-8f30-e850bbac5820'	System	10 Jan 2021 13:39:05
User entered 'No (N)'	System	10 Jan 2021 13:39:05

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-01-10T07:39:02', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '7c057e69-36ac-475d-8f30-e850bbac5820'	System	10 Jan 2021 13:39:05
User entered '10 Jan 2021 07:39:02'	System	10 Jan 2021 13:39:05

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-01-17T08:19:46', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'eb1c7852-d3e7-4f6d-b8ea-a4243b8a6e42'	System	17 Jan 2021 14:19:57
User entered 'No (N)'	System	17 Jan 2021 14:19:57

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-01-17T08:19:49', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'eb1c7852-d3e7-4f6d-b8ea-a4243b8a6e42'	System	17 Jan 2021 14:19:57
User entered 'No (N)'	System	17 Jan 2021 14:19:57

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-01-17T08:19:52', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'eb1c7852-d3e7-4f6d-b8ea-a4243b8a6e42'	System	17 Jan 2021 14:19:57
User entered '17 Jan 2021 08:19:52'	System	17 Jan 2021 14:19:57

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-01-24T09:47:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '69f63fec-ce83-4b83-9055-af3180eb5c12'	System	24 Jan 2021 15:47:19
User entered 'No (N)'	System	24 Jan 2021 15:47:19

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-01-24T09:47:12', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '69f63fec-ce83-4b83-9055-af3180eb5c12'	System	24 Jan 2021 15:47:19
User entered 'No (N)'	System	24 Jan 2021 15:47:19

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-01-24T09:47:15', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '69f63fec-ce83-4b83-9055-af3180eb5c12'	System	24 Jan 2021 15:47:19
User entered '24 Jan 2021 09:47:15'	System	24 Jan 2021 15:47:19

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-02-01T07:20:32', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5b8cc412-70ba-4183-b422-aa448a94ea79'	System	01 Feb 2021 13:20:44
User entered 'No (N)'	System	01 Feb 2021 13:20:44

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-02-01T07:20:35', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5b8cc412-70ba-4183-b422-aa448a94ea79'	System	01 Feb 2021 13:20:44
User entered 'No (N)'	System	01 Feb 2021 13:20:44

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-02-01T07:20:40', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '5b8cc412-70ba-4183-b422-aa448a94ea79'	System	01 Feb 2021 13:20:44
User entered '01 Feb 2021 07:20:40'	System	01 Feb 2021 13:20:44

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-02-07T08:22:42', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '85553113-a5c1-46e5-8568-5f1c7cbe8a4d'	System	07 Feb 2021 14:22:52
User entered 'No (N)'	System	07 Feb 2021 14:22:52

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-02-07T08:22:45', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '85553113-a5c1-46e5-8568-5f1c7cbe8a4d'	System	07 Feb 2021 14:22:52
User entered 'No (N)'	System	07 Feb 2021 14:22:52

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-02-07T08:22:48', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '85553113-a5c1-46e5-8568-5f1c7cbe8a4d'	System	07 Feb 2021 14:22:52
User entered '07 Feb 2021 08:22:48'	System	07 Feb 2021 14:22:52

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-02-14T07:30:03', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '808bd4f4-d555-45a2-8c4b-de14ba549f3b'	System	14 Feb 2021 13:30:15
User entered 'No (N)'	System	14 Feb 2021 13:30:15

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-02-14T07:30:06', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '808bd4f4-d555-45a2-8c4b-de14ba549f3b'	System	14 Feb 2021 13:30:15
User entered 'No (N)'	System	14 Feb 2021 13:30:15

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-02-14T07:30:10', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '808bd4f4-d555-45a2-8c4b-de14ba549f3b'	System	14 Feb 2021 13:30:15
User entered '14 Feb 2021 07:30:10'	System	14 Feb 2021 13:30:15

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-02-28T00:15:18-06:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '98691909-10ba-4426-bf74-fdd8088dccbb' User entered 'No (N)'	System	28 Feb 2021 06:15:34

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-02-28T00:15:27-06:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '98691909-10ba-4426-bf74-fdd8088dccbb'	System	28 Feb 2021 06:15:34
User entered 'No (N)'	System	28 Feb 2021 06:15:34

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-02-28T00:15:31-06:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '98691909-10ba-4426-bf74-fdd8088dccbb' User entered '28 Feb 2021 00:15:31'	System	28 Feb 2021 06:15:34
	System	28 Feb 2021 06:15:34

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-03-14T08:05:56-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6536e291-f22a-4a53-9af3-25e364ad666a' User entered 'No (N)'	System	14 Mar 2021 13:06:05
	System	14 Mar 2021 13:06:05

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-03-14T08:06:00-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6536e291-f22a-4a53-9af3-25e364ad666a'	System	14 Mar 2021 13:06:05
User entered 'No (N)'	System	14 Mar 2021 13:06:05

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-03-14T08:06:02-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '6536e291-f22a-4a53-9af3-25e364ad666a' User entered '14 Mar 2021 08:06:02'	System	14 Mar 2021 13:06:05
	System	14 Mar 2021 13:06:05

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-03-21T07:29:19-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '586375b3-6505-482f-8693-38be050e2cf0' User entered 'No (N)'	System	21 Mar 2021 12:29:29
	System	21 Mar 2021 12:29:29

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-03-21T07:29:22-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '586375b3-6505-482f-8693-38be050e2cf0'	System	21 Mar 2021 12:29:29
User entered 'No (N)'	System	21 Mar 2021 12:29:29

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-03-21T07:29:25-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '586375b3-6505-482f-8693-38be050e2cf0' User entered '21 Mar 2021 07:29:25'	System	21 Mar 2021 12:29:29
	System	21 Mar 2021 12:29:29

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-03-28T07:13:34-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '084e333e-641a-4b5f-a1da-48f1f45f1a88'	System	28 Mar 2021 12:13:47
User entered 'No (N)'	System	28 Mar 2021 12:13:47

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-03-28T07:13:36-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '084e333e-641a-4b5f-a1da-48f1f45f1a88'	System	28 Mar 2021 12:13:47
User entered 'No (N)'	System	28 Mar 2021 12:13:47

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-03-28T07:13:43-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '084e333e-641a-4b5f-a1da-48f1f45f1a88' User entered '28 Mar 2021 07:13:43'	System	28 Mar 2021 12:13:47
	System	28 Mar 2021 12:13:47

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-04-04T08:01:40-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '90deaaaa-a110-4c97-98c5-c5d6a91ffd64' User entered 'No (N)'	System	04 Apr 2021 13:01:53
	System	04 Apr 2021 13:01:53

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-04-04T08:01:43-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '90deaaaa-a110-4c97-98c5-c5d6a91ffd64'	System	04 Apr 2021 13:01:53
User entered 'No (N)'	System	04 Apr 2021 13:01:53

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-04-04T08:01:47-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '90deaaaa-a110-4c97-98c5-c5d6a91ffd64'	System	04 Apr 2021 13:01:53
User entered '04 Apr 2021 08:01:47'	System	04 Apr 2021 13:01:53

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-04-11T07:27:29-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'aa9522a4-150c-40b3-87ed-64c178caec12'	System	11 Apr 2021 12:27:38
User entered 'No (N)'	System	11 Apr 2021 12:27:38

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-04-11T07:27:32-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'aa9522a4-150c-40b3-87ed-64c178caec12'	System	11 Apr 2021 12:27:38
User entered 'No (N)'	System	11 Apr 2021 12:27:38

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-04-11T07:27:35-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'aa9522a4-150c-40b3-87ed-64c178caec12'	System	11 Apr 2021 12:27:38
User entered '11 Apr 2021 07:27:35'	System	11 Apr 2021 12:27:38

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-04-20T07:24:43-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'cd27c555-a557-45f6-a59e-d9164be66315'	System	20 Apr 2021 12:24:53
User entered 'No (N)'	System	20 Apr 2021 12:24:53

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-04-20T07:24:45-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'cd27c555-a557-45f6-a59e-d9164be66315'	System	20 Apr 2021 12:24:53
User entered 'No (N)'	System	20 Apr 2021 12:24:53

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-04-20T07:24:47-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'cd27c555-a557-45f6-a59e-d9164be66315' User entered '20 Apr 2021 07:24:47'	System	20 Apr 2021 12:24:53
	System	20 Apr 2021 12:24:53

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-04-25T06:41:19-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '1d5298c4-0f49-4156-be66-136d6ed0cd20'	System	25 Apr 2021 11:41:45
User entered 'No (N)'	System	25 Apr 2021 11:41:45

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-04-25T06:41:21-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '1d5298c4-0f49-4156-be66-136d6ed0cd20'	System	25 Apr 2021 11:41:45
User entered 'No (N)'	System	25 Apr 2021 11:41:45

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-04-25T06:41:41-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '1d5298c4-0f49-4156-be66-136d6ed0cd20' User entered '25 Apr 2021 06:41:41'	System	25 Apr 2021 11:41:45
	System	25 Apr 2021 11:41:45

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-05-02T07:41:02-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '10ab9d22-416b-4b9f-b5be-414005edebbe' User entered 'Yes (Y)'	System	02 May 2021 12:41:46
	System	02 May 2021 12:41:46

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

Have you been exposed to someone with 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 (58240fda69da0960)', Time: '2021-05-02T07:41:07-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '10ab9d22-416b-4b9f-b5be-414005edebbe'	System	02 May 2021 12:41:46
User entered 'No (N)'	System	02 May 2021 12:41:46

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

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 (58240fda69da0960)', Time: '2021-05-02T07:41:13-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '10ab9d22-416b-4b9f-b5be-414005edebbe'	System	02 May 2021 12:41:46
User entered 'No (N)'	System	02 May 2021 12:41:46

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[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 (58240fda69da0960)', Time: '2021-05-02T07:41:18-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '10ab9d22-416b-4b9f-b5be-414005edebbe' User entered 'Yes (Y)'	System	02 May 2021 12:41:46
	System	02 May 2021 12:41:46

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Please 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 (58240fda69da0960)', Time: '2021-05-02T07:41:25-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '10ab9d22-416b-4b9f-b5be-414005edebbe'	System	02 May 2021 12:41:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 May 2021 12:41:46

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-05-02T07:41:33-05:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: '10ab9d22-416b-4b9f-b5be-414005edebbe'	System	02 May 2021 12:41:46
User entered '02 May 2021 07:41:33'	System	02 May 2021 12:41:46

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 03:52:25

US3862128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:06:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:52:25
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 03:52:25

US3862128

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:06:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-02-28T00:15:41-06:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ed9ea1ce-1401-42e4-a87e-0c2bffdd1b20'	System	28 Feb 2021 06:15:50
User entered 'No (N)'	System	28 Feb 2021 06:15:50

US3862128

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:06:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58240fda69da0960)', Time: '2021-02-28T00:15:46-06:00', User OID: 'PatientReportedOutcome (US3862128)', ODM File OID: 'ed9ea1ce-1401-42e4-a87e-0c2bffdd1b20'	System	28 Feb 2021 06:15:50
User entered '28 Feb 2021 00:15:46'	System	28 Feb 2021 06:15:50

US3862128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:42
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:02:55
User entered 'Yes (Y)'	Chanei Henry (b) (4)	30 Nov 2020 18:25:04

US3862128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:02:55
User entered '30 Nov 2020'	Chanei Henry (b) (4)	30 Nov 2020 18:25:04
	(b) (4)	

US3862128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:02:55
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4) (b) (4)	30 Nov 2020 18:25:04

US3862128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 22:02:55
User entered empty.	Chanei Henry (b) (4)	30 Nov 2020 18:25:04
	(b) (4)	

US3862128

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:42
DataPoint Verified.	(b) (4)	19 Jan 2021 22:02:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 18:25:08
	Chanei Henry (b) (4)	
	(b) (4)	

US3862128

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:05
User entered '1'	System	30 Nov 2020 18:25:08

US3862128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4)	30 Dec 2020 17:47:52
	Carrie Kibler (b) (4)	
	(b) (4)	

US3862128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '30 Dec 2020'	(b) (4)	30 Dec 2020 17:47:52
	Carrie Kibler (b) (4)	
	(b) (4)	

US3862128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Dec 2020 17:47:52

US3862128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	30 Dec 2020 17:47:52
	Carrie Kibler (b) (4)	
	(b) (4)	

US3862128

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4)	30 Dec 2020 17:47:56
	Carrie Kibler (b) (4)	
	(b) (4)	

US3862128

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
User entered '1'	System	30 Dec 2020 17:47:56

US3862128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4)	02 Feb 2021 20:58:02
	Carrie Kibler (b) (4)	
	(b) (4)	

US3862128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '02 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Feb 2021 20:58:02

US3862128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Feb 2021 20:58:02

US3862128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	02 Feb 2021 20:58:02
	Carrie Kibler (b) (4)	
	(b) (4)	

US3862128

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
DataPoint Verified.		14 Apr 2021 15:28:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Feb 2021 20:58:06

US3862128

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:34:00
User entered '1'	System	02 Feb 2021 20:58:06

US3862128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:07
DataPoint Verified.		14 Apr 2021 15:29:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 20:10:05

US3862128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:07
DataPoint Verified.		14 Apr 2021 15:29:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '03 Mar 2021' reason for change: Data Entry Error	Carrie Kibler (b) (4)	03 Mar 2021 22:05:23
	(b) (4)	
User entered '3 Mar 2021'	(b) (4), (b) (6)	03 Mar 2021 20:10:05

US3862128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:07
DataPoint Verified.		14 Apr 2021 15:29:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Mar 2021 20:10:05

US3862128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:07
DataPoint Verified.		14 Apr 2021 15:29:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:10:05

US3862128

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:07
DataPoint Verified.		14 Apr 2021 15:30:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:10:17

US3862128

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:07
User entered '1'	System	03 Mar 2021 20:10:17

US3862128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:31:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 18:50:40

US3862128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:31:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '31 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 18:50:40

US3862128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:31:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 18:50:40

US3862128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	31 Mar 2021 18:50:40

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:30:20

US3862128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:27

US3862128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:39:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:27

US3862128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:40:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:48

US3862128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:40:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '31 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:48

US3862128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:40:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '14:04'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:30:48

US3862128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 14:04'	System	31 Mar 2021 19:30:48

US3862128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:40:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Mar 2021 19:31:00

US3862128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 19:31:00

US3862128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:04:01

US3862128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:04:01

US3862128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:04:01

US3862128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:06:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:04:01

US3862128

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Apr 2021 20:04:07

US3862128

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:06:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 20:04:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:06:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 16:48:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '2 Nov 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:39

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:06:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 16:55:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '09:30'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:39

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:06:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '2 Nov 2020 09:30'	System	04 Nov 2020 21:23:39

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:06:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 16:55:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Thea Marie Cordero	04 Nov 2020 21:23:39
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:06:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 16:55:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:39

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
Query 'Please file symptom logs in source with Illness Visit. ' canceled (Site from CRA).		14 Apr 2021 17:08:15
User opened query 'Please file symptom logs in source with Illness Visit. ' (Site from CRA).		14 Apr 2021 17:01:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Day 1 (Day 1)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '19 Oct 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:25:56

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:25:56

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User closed query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' (Site from CRA).		16 Apr 2021 16:05:33
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:11
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
	(b) (4)	
Query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' answered with 'updated in edc. ' (Site from CRA).	Carrie Kibler (b) (4)	14 Apr 2021 19:41:36
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	14 Apr 2021 19:41:29
	(b) (4)	
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:41:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:41:29
	(b) (4)	
User opened query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:16:51
Query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave Assessment Not Done box empty. ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:16:44
User opened query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave Assessment Not Done box empty. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:15:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:41:29
User entered empty.	System	04 Nov 2020 21:25:56

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User closed query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' (Site from CRA).		16 Apr 2021 16:05:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:13
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
	(b) (4)	
Query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' answered with 'updated in edc.' (Site from CRA).	Carrie Kibler (b) (4)	14 Apr 2021 19:41:40
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	14 Apr 2021 19:41:29
	(b) (4)	
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:41:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:41:29
	(b) (4)	
User opened query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:16:59
Query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave Assessment Not Done box empty. ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:16:54
User opened query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave Assessment Not Done box empty. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:15:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:25:56

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:25:56

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:25:56

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:25:56

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:25:56
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 2 (Day 2)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:26:54

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '20 Oct 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:26:54

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:04:23
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:41:46
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:41:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Apr 2021 19:41:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	04 Nov 2020 21:26:54

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:41:46
User entered empty.	System	04 Nov 2020 21:26:54

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:04:23
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:41:46
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:41:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Apr 2021 19:41:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	04 Nov 2020 21:26:54

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:26:54

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Mild (Mild)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:26:54

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:26:54
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 3 (Day 3)'	(b) (4) Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '21 Oct 2020'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:04:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:41:52
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:41:52
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:41:52
User entered empty.	System	04 Nov 2020 21:27:47

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:04:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:41:52
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:41:52
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:41:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:27:47

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:27:47

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:27:47
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 4 (Day 4)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:29:08

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '22 Oct 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:29:08

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:29:08

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:41:57
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:41:57
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:41:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:41:57
User entered empty.	System	04 Nov 2020 21:29:08

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:05:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:41:57
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:41:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Apr 2021 19:41:57
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	04 Nov 2020 21:29:08
	Thea Marie Cordero	
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:29:08

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:29:08

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:29:08

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:29:08

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:29:08
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 5 (Day 5)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:31:21

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '23 Oct 2020'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:31:21

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:24
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:02
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:02
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:02
User entered empty.	System	04 Nov 2020 21:31:21

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:24
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:02
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:02
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:02
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:31:21

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:31:21

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:31:21

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:31:21
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 6 (Day 6)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:32:18

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '24 Oct 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:32:18

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:05:22
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:08
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:08
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	(b) (4)	
	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	
	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:08
User entered empty.	System	04 Nov 2020 21:32:18

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:22
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:08
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:08
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:32:18

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:32:18

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:32:18

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:32:18

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:32:18
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 7 (Day 7)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:33:15

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '25 Oct 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:33:15

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:05:20
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:13
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:13
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	(b) (4)	
	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	
	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:13
User entered empty.	System	04 Nov 2020 21:33:15

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:05:20
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:42:13
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:42:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Apr 2021 19:42:13
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	04 Nov 2020 21:33:15

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:33:15

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:33:15

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:33:15

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:33:15

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:33:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 8 (Day 8)'	(b) (4) Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '26 Oct 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:34:15

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:34:15

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:18
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:42:19
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:42:19
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Apr 2021 19:42:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	04 Nov 2020 21:34:15

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:19
User entered empty.	System	04 Nov 2020 21:34:15

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:18
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:19
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:19
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Mild (Mild)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:34:15

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:34:15
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 9 (Day 9)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:35:23

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '27 Oct 2020'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:16
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:24
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:24
User entered empty.	System	04 Nov 2020 21:35:23

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:16
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:24
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:35:23

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:35:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:35:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Mild (Mild)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:35:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:35:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 10 (Day 10)'	(b) (4) Thea Marie Cordero	04 Nov 2020 21:36:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '28 Oct 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:05:14
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:42:30
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:42:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Apr 2021 19:42:30
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	04 Nov 2020 21:36:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:30
User entered empty.	System	04 Nov 2020 21:36:23

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:14
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:30
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:30
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:36:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:36:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:36:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:36:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:36:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:36:23
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:36:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:36:23

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:36:23
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 11 (Day 11)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '29 Oct 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:05:12
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:35
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:35
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	(b) (4)	
	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	
	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:35
User entered empty.	System	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:05:12
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:35
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:35
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Mild (Mild)'	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Thea Marie Cordero	04 Nov 2020 21:40:04
User entered empty.	(b) (4)	
	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:40:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 21:40:04
User entered '30 Oct 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:38:07
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:10
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:40
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:40
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.		
	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	
	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:40
User entered empty.	System	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:05:10
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:42:40
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:42:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Apr 2021 19:42:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	04 Nov 2020 21:38:07
	Thea Marie Cordero	
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Thea Marie Cordero	04 Nov 2020 21:40:04
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	04 Nov 2020 21:40:04
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:38:07

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 13 (Day 13)'	(b) (4) Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '31 Oct 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:41:03

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:03
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:42:47
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:42:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Apr 2021 19:42:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	04 Nov 2020 21:41:03

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:47
User entered empty.	System	04 Nov 2020 21:41:03

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:03
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:47
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:47
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Mild (Mild)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:41:03

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:41:03

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:41:03
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 14 (Day 14)'	(b) (4) Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:05:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:58
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:42:58
User entered '01 Nov 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '1 Nov 2020'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:42:16

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User closed query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' (Site from CRA).		16 Apr 2021 16:04:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:38
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
	(b) (4)	
Query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' answered with 'updated in edc.' (Site from CRA).	Carrie Kibler (b) (4)	14 Apr 2021 19:43:04
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	14 Apr 2021 19:42:58
	(b) (4)	
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:42:58
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:58
	(b) (4)	
User opened query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:16:33
Query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave Assessment Not Done box empty. ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:16:27
User opened query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave Assessment Not Done box empty. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:15:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	14 Apr 2021 19:42:58
User entered empty.	System	04 Nov 2020 21:42:16

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User closed query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' (Site from CRA).		16 Apr 2021 16:04:42
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:41
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
	(b) (4)	
Query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' answered with 'updated in edc. ' (Site from CRA).	Carrie Kibler (b) (4)	14 Apr 2021 19:43:09
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	14 Apr 2021 19:42:58
	(b) (4)	
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:42:58
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:42:58
	(b) (4)	
User opened query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave "Assessment Not Done" box empty. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:16:24
Query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave Assessment Not Done box empty. ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:16:03
User opened query 'please indicate "Not Done" for O2 Saturation and Temperature for all Symptom Days these procedure were not done. Please leave Assessment Not Done box empty. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 17:15:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:42:16

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:42:16

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:42:16

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:42:16

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Mild (Mild)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:42:16

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:42:16

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:42:16
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 15 (Day 15)'	(b) (4) Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:06:21
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:43:16
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:43:16
	(b) (4)	
User entered '02 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:43:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '2 Nov 2020'	Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '99'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '98.6' F	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:43:41

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:43:41
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 16 (Day 16)'	(b) (4) Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:06:21
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:43:22
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:43:22
	(b) (4)	
User entered '03 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:43:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '3 Nov 2020'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '97'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:45:06

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	04 Nov 2020 21:45:06

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '97.5' F	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:45:06

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:45:06

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:45:06

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:45:06

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:45:06

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:45:06

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:45:06

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:45:06
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 17 (Day 17)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.	(b) (4)	16 Apr 2021 16:06:21
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	14 Apr 2021 19:43:29
Signature has been broken.	Carrie Kibler (b) (4)	14 Apr 2021 19:43:29
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4)	14 Apr 2021 19:43:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '4 Nov 2020'	(b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '99'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '97.5' F	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:47:36
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:47:36
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:47:36
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:47:36
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:47:36
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:47:36
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:47:36
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	04 Nov 2020 21:47:36
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:47:36

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 18 (Day 18)'	(b) (4) Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:06:21
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:43:35
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:43:35
	(b) (4)	
User entered '05 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:43:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '5 Nov 2020'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:08:01

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '98'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:08:01

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	06 Nov 2020 16:08:01

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '96.7' F	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:08:01

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:08:01

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:08:01

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:08:01
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:08:01

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:08:01

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:08:01

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Day 19 (Day 19)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:09:14

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		16 Apr 2021 16:06:21
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:43:41
Signature has been broken.	(b) (4)	
	Carrie Kibler (b) (4)	14 Apr 2021 19:43:41
	(b) (4)	
User entered '06 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	14 Apr 2021 19:43:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '6 Nov 2020'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:09:14

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '98'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:09:14

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '%'	System	06 Nov 2020 16:09:14

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '97.8' F	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:09:14

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:09:14

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:09:14

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'None (None)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 16:09:14

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 10 Jun 2021 10:06:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:08:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'None (None)'	Thea Marie Cordero	06 Nov 2020 16:09:14
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '2 Nov 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:59

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

[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 20:51:46
DataPoint Verified.		14 Apr 2021 17:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:59

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

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 20:51:46
DataPoint Verified.		14 Apr 2021 17:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:32:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 21:32:12
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	06 Nov 2020 21:32:12
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:23:59
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:59

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '2 Nov 2020'	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:59

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:59

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:59

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

[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 20:51:46
DataPoint Verified.		14 Apr 2021 17:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:32:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 21:32:12
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	06 Nov 2020 21:32:12
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:23:59
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:59

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:59

US3862128

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Thea Marie Cordero (b) (4)	04 Nov 2020 21:23:59

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:06:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
User entered '0'	System	06 Nov 2020 21:32:12

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:06:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:51:46
DataPoint Verified.		14 Apr 2021 17:12:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:04:55

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:06:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
User accepted default value 'Day 3 (Day 3)'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:06:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 04Nov2020 for Day 3 is recorded in EDC, however sample is reported with 03Nov2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 12:08:38
Query 'Per GCL Lab Recon: Saliva: Sample dated 04Nov2020 for Day 3 is recorded in EDC, however sample is reported with 03Nov2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'saliva collected november 4' (Site from DM).	Carrie Kibler (b) (4)	02 Feb 2021 21:36:29
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 04Nov2020 for Day 3 is recorded in EDC, however sample is reported with 03Nov2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:15:26
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:06:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:26:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:38:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' answered with 'Per monitor instruction, this query is not needed.' (Site from DM).	Sandra Francisco (b) (4)	22 Mar 2021 13:24:41
User entered '04 Nov 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	22 Mar 2021 13:24:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 still not received at PPD central lab, if sample shipped then please provide accession number, tracking number and shipping date in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:29:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 and 06NOV2020 is recorded under Illness visit 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)	09 Feb 2021 12:08:36

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:06:48

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 and 06NOV2020 is recorded under Illness visit 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.' answered with '1F60GHU is the accession number.' (Site from DM).	Carrie Kibler (b) (4)	02 Feb 2021 21:37:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 and 06NOV2020 is recorded under Illness visit 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)	07 Dec 2020 09:36:18
User entered '4 Nov 2020'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:06:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
User accepted default value 'Day 5 (Day 5)'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:06:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:06:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '6 Nov 2020'	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:06:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
User accepted default value 'Day 7 (Day 7)'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:06:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:06:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:06:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
User accepted default value 'Day 9 (Day 9)'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:06:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:06:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered empty.	(b) (4)	06 Nov 2020 21:36:51

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:06:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
User accepted default value 'Day 14 (Day 14)'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:06:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:06:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:06:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
User accepted default value 'Day 21 (Day 21)'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:06:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:06:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:06:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
User accepted default value 'Day 28 (Day 28)'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:51

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:06:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

US3862128

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:06:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:28
DataPoint Verified.		14 Apr 2021 17:26:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Nov 2020 21:36:51
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:24:55
DataPoint Verified.		14 Apr 2021 16:17:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 21:34:48

US3862128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:24:55
DataPoint Verified.		14 Apr 2021 16:17:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 04:08:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'SALIVA SAMPLE DAY 3: COLLECTED AT HOME BY SUBJECT 04 NOV 2020 SALIVA SAMPLE DAY 5: COLLECTED AT HOME BY SUBJECT 06 NOV 2020 2 SAMPLES WERE DROPPED OFF BY SUBJECT ON 16 NOV 2020' (Site from DM).	Thea Marie Cordero (b) (4)	30 Nov 2020 21:57:42
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:25:37
User entered '2 Nov 2020'	Thea Marie Cordero (b) (4)	06 Nov 2020 21:34:48

US3862128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[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 12:24:55
DataPoint Verified.		14 Apr 2021 16:17:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Thea Marie Cordero	06 Nov 2020 21:34:48
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:24:55
User entered 'SICKD1'	System	06 Nov 2020 21:34:48

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 21:35:45

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '2 Nov 2020'	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '09:30'	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
User entered '2 Nov 2020 09:30'	System	06 Nov 2020 21:35:45

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '166.3' cm	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	
DataPoint set to visible.	System	06 Nov 2020 21:34:48

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '169' lb	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	
DataPoint set to visible.	System	06 Nov 2020 21:34:48

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '98.6' F	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Oral (Oral)'	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '67'	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
User entered 'bpm'	System	06 Nov 2020 21:35:45

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '16'	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
User entered 'breaths/min'	System	06 Nov 2020 21:35:45

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '126'	Thea Marie Cordero	06 Nov 2020 21:35:45
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
User entered 'mmHg'	System	06 Nov 2020 21:35:45

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
DataPoint Verified.		14 Apr 2021 16:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '77'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 21:35:45

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02
User entered 'mmHg'	System	06 Nov 2020 21:35:45

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02

US3862128

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:06:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:02

US3862128

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:09
DataPoint Verified.		14 Apr 2021 16:23:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	06 Nov 2020 21:35:59
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:06:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:09
DataPoint Verified.		14 Apr 2021 16:23:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '2 Nov 2020'	Thea Marie Cordero	06 Nov 2020 21:35:59
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:06:48

[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 12:25:20
DataPoint Verified.		14 Apr 2021 16:23:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	06 Nov 2020 21:36:08
	(b) (4)	

US3862128

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:06:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:25:20
DataPoint Verified.		14 Apr 2021 16:23:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '2 Nov 2020'	(b) (4) Thea Marie Cordero (b) (4)	06 Nov 2020 21:36:08

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:45:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4)	22 Feb 2021 21:54:17
	Carrie Kibler (b) (4)	
	(b) (4)	

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:45:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '22 Feb 2021'	(b) (4)	
	Carrie Kibler (b) (4)	22 Feb 2021 21:54:17
	(b) (4)	

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[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 10:28:16
DataPoint Verified.		14 Apr 2021 15:45:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Clinic (Clinic)'	(b) (4)	
	Carrie Kibler (b) (4)	22 Feb 2021 21:54:17
	(b) (4)	

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:06:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 21:54:17

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:48:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '22 Feb 2021'	Carrie Kibler (b) (4)	22 Feb 2021 21:53:57
	(b) (4)	

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:21:38

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:48:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 21:53:57

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:21:38

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:48:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '22 Feb 2021'	(b) (4)	
	Carrie Kibler (b) (4)	22 Feb 2021 21:53:57
	(b) (4)	

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:48:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4)	22 Feb 2021 21:53:57
	(b) (4)	

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:48:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4)	22 Feb 2021 21:53:57
	(b) (4)	

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:48:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4)	22 Feb 2021 21:53:57
	(b) (4)	

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:48:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'No (N)'	(b) (4)	22 Feb 2021 21:53:57
	Carrie Kibler (b) (4)	
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
User entered empty.	System	22 Feb 2021 21:53:57

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:06:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
User entered empty.	System	22 Feb 2021 21:53:57

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:50:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 21:54:07

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:50:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 05:38:43
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' answered with 'Per monitor instruction, this query is not needed.' (Site from DM).	Sandra Francisco (b) (4)	22 Mar 2021 13:23:09
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 07:36:24
User entered '22 Feb 2021'	Carrie Kibler (b) (4)	22 Feb 2021 21:54:07

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:50:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '14:22'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 21:54:07

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:06:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
User entered '22 Feb 2021 14:22'	System	22 Feb 2021 21:54:07

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:06:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:50:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 21:54:40

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:06:48

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:50:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '22 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 21:54:40

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:06:48

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
DataPoint Verified.		14 Apr 2021 15:50:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '14:21'	(b) (4)	
	Carrie Kibler (b) (4)	22 Feb 2021 21:54:40
	(b) (4)	

US3862128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:06:48

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:16
User entered '22 Feb 2021 14:21'	System	22 Feb 2021 21:54:40

US3862128

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:06:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:35:00
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	15 Apr 2021 21:42:56
User closed query 'Per Diary Dose 2, 'redness' continued past Day 7. Please consider adding an AE as per protocol and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:03:10
Query 'Per Diary Dose 2, 'redness' continued past Day 7. Please consider adding an AE as per protocol and update accordingly.' answered with 'AE#02 has been created to address this query. "(redness)" was added to EDC and source to AE#02 entry on 22MAR2021.' (Site from CRA).	Sandra Francisco (b) (4) (b) (4)	22 Mar 2021 13:28:06
User opened query 'Per Diary Dose 2, 'redness' continued past Day 7. Please consider adding an AE as per protocol and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 04:21:40
User closed query 'Per Diary Dose 2, 'redness' continued past Day 7. Please consider adding an AE as per protocol and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 04:21:40
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 8; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	(b) (4), (b) (6)	06 Feb 2021 11:09:45
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 8; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	(b) (4), (b) (6)	06 Feb 2021 11:09:08
' (Site from DM).		
Query 'Per Diary Dose 2, 'redness' continued past Day 7. Please consider adding an AE as per protocol and update accordingly.' answered with 'to add' (Site from CRA).	Carrie Kibler (b) (4) (b) (4)	02 Feb 2021 21:21:55

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:06:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per Diary Dose 2, 'redness' continued past Day 7. Please consider adding an AE as per protocol and update accordingly. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	08 Dec 2020 18:19:16
	(b) (4), (b) (6) (b) (4)	08 Dec 2020 18:18:22
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:20:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:54:34
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 21:13:32
Data point term sent to Coder	(b) (4)	
DataPoint Un-verified.	System	02 Feb 2021 21:12:14
Coding entries removed.	Carrie Kibler (b) (4)	02 Feb 2021 21:12:01
User entered 'exacerbation of seasonal allergies' reason for change: New Information	(b) (4)	
DataPoint Verified.	Carrie Kibler (b) (4)	02 Feb 2021 21:12:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\\23.0.	(b) (4), (b) (6)	19 Jan 2021 21:34:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 21:38:29
Data point term sent to Coder	(b) (4)	
User entered 'Rhinorrhea'	System	04 Nov 2020 21:22:52
	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:54:35
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
User closed query 'Please update to Yes, since subject was seen in clinic for this AE (Illness Visit).' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 04:20:46
Query 'Please update to Yes, since subject was seen in clinic for this AE (Illness Visit).' answered with 'updated' (Site from CRA).	Carrie Kibler (b) (4) (b) (4)	02 Feb 2021 21:03:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	02 Feb 2021 21:02:50
User opened query 'Please update to Yes, since subject was seen in clinic for this AE (Illness Visit).' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 21:34:22
User entered 'No (N)'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:27
User entered 'No (N)'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:30
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 18:56:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 18:56:38
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 18:56:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:21:59
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:33
User entered '19 Oct 2020'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:34:34
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:21:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4)	19 Jan 2021 21:34:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 16:13:13
User entered 'Yes (Y)'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:34:38
User entered '5 Nov 2020' reason for change: Data Entry Error	Thea Marie Cordero	06 Nov 2020 16:13:13
User entered empty.	(b) (4)	
	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:41
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:21:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

Severity

Audit	User	Time (GMT)
User closed query 'Per DM RQ: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:03:21
Query 'Per DM RQ: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' answered with 'no changes will be done in data grade 1 not worsening Ae recovered resolved' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 17:04:32
User opened query 'Per DM RQ: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:47:39
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:45:24
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' answered with 'Per protocol, this can be graded as Grade 1/mild. No changes needed.' (Site from DM).	Sandra Francisco	22 Mar 2021 13:26:42
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:38:39
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:42

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:44
User entered 'No (N)'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:34:47
User entered '0'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:48
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:50
User entered '0'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:51
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4)	19 Jan 2021 21:34:52
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 21:34:52
	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:34:54
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:55
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:34:57
User entered '0'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:34:58
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:34:59
User entered '0'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:35:01
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:35:03
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:21:59

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4)	19 Jan 2021 21:35:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	04 Nov 2020 21:21:59
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:35:17
User entered '1'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:35:21
User entered '0'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4)	19 Jan 2021 21:35:24
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 21:35:24
	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 21:35:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Thea Marie Cordero	06 Nov 2020 16:13:13
Data Entry Error	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:35:27
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:35:28
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:21:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 21:21:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:06:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 21:02:50
User entered '0'	System	04 Nov 2020 21:21:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint Verified.		14 Apr 2021 15:55:56
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 16:10:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	29 Mar 2021 16:10:22
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:16:54
Data point term sent to Coder	System	22 Mar 2021 13:26:10
User closed query 'For coding purposes, please specify type of reaction for term PROLONGED INJECTION SITE REACTION' (Site from System).	System	22 Mar 2021 13:26:07
Query 'For coding purposes, please specify type of reaction for term PROLONGED INJECTION SITE REACTION' answered with 'updated EDC and source with "(redness)" on 22MAR2021' (Site from System).	Sandra Francisco (b) (4)	22 Mar 2021 13:26:07
Coding entries removed.	Sandra Francisco (b) (4)	22 Mar 2021 13:25:43
User entered 'PROLONGED INJECTION SITE REACTION (redness)' reason for change: New Information	Sandra Francisco (b) (4)	22 Mar 2021 13:25:43
User opened query 'For coding purposes, please specify type of reaction for term PROLONGED INJECTION SITE REACTION' (Site from System).	Coder Import (b) (4)	21 Mar 2021 19:46:30
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site reaction, LLT: Injection site reaction - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 07:58:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 07:58:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #1 (RHINORRHEA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 17:07:27
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #1 (RHINORRHEA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.	Carrie Kibler (b) (4)	02 Feb 2021 21:29:57
' answered with 'combined rhinorrhea and dry cough into ae number one as exacerbation of seasonal allergies and added prolonged injection site reaction due to redness reported after second dose. late entry made.' (Site from DM).	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 21:29:30
DataPoint Un-verified.	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
	(b) (4)	
Coding entries removed.	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
	(b) (4)	
User entered 'prolonged injection site reaction' reason for change: New Information	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 21:28:29
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 21:12:14
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:35:40
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #1 (RHINORRHEA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.		28 Dec 2020 01:55:01
' (Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Dry cough - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 21:23:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 21:23:30
Data point term sent to Coder	System	04 Nov 2020 21:22:53
User entered 'Dry cough'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:22:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint Verified.		14 Apr 2021 15:55:59
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Feb 2021 21:03:09
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	04 Nov 2020 21:22:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint Verified.		16 Apr 2021 17:23:31
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM). User signature succeeded.		16 Apr 2021 12:49:42
	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	15 Apr 2021 20:37:49
	(b) (4)	
Signature has been broken.	Carrie Kibler (b) (4)	15 Apr 2021 20:37:49
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	15 Apr 2021 20:37:49
	(b) (4)	
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'ANSWER REMAIN AS IS. THIS IS AFTER THE 7 DAY POST REACTOGENICITY PERIOD THEREFORE THIS IS NOT ANYMORE A SOLICITED ADVERSE REACTION AND WAS REPORTED AS AN AE' (Site from DM).	Thea Marie Cordero (b) (4)	05 Apr 2021 23:18:16
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	04 Apr 2021 16:18:11
	Thea Marie Cordero (b) (4)	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:35:46

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:22:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:35:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 18:56:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 18:56:56
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 18:56:56
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Nov 2020 21:22:51
User entered empty.	System	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint Verified.		16 Apr 2021 17:23:35
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom PROLONGED INJECTION SITE REACTION (REDNESS) on 02OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).		16 Apr 2021 12:49:39
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
DataPoint Un-verified.	(b) (4) Carrie Kibler (b) (4)	15 Apr 2021 20:37:49
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	15 Apr 2021 20:37:49
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	15 Apr 2021 20:37:49
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:55:49
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom PROLONGED INJECTION SITE REACTION (REDNESS) on 02OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'CORRECT DATE, WILL REMAIN AS IS' (Site from DM).	Thea Marie Cordero (b) (4)	05 Apr 2021 23:18:19
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom PROLONGED INJECTION SITE REACTION (REDNESS) on 02OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 16:18:38
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:16:54
DataPoint Un-verified.	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	02 Feb 2021 21:29:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:35:49
User entered '19 Oct 2020'	Thea Marie Cordero (b) (4)	04 Nov 2020 21:22:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint Verified.	(b) (4)	16 Apr 2021 17:23:37
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Apr 2021 20:40:41
DataPoint Un-verified.	System	15 Apr 2021 20:40:41
Signature has been broken.	Carrie Kibler (b) (4)	15 Apr 2021 20:40:41
User entered '20:08' reason for change: Per Query Resolution	Carrie Kibler (b) (4)	15 Apr 2021 20:40:41
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Apr 2021 20:37:49
User signature succeeded.	System	15 Apr 2021 20:37:49
DataPoint activated with code reason code Data required.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint inactivated with code reason code Data not required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint Verified.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
User entered empty.	(b) (4)	02 Feb 2021 21:11:41
	(b) (4), (b) (6)	19 Jan 2021 21:35:51
	(b) (4)	04 Nov 2020 21:22:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User entered '02 Oct 2020 20:08'	System	15 Apr 2021 20:40:41
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	02 Feb 2021 21:11:41
User entered empty.	System	04 Nov 2020 21:22:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:35:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 16:13:48
User entered 'Yes (Y)'	Thea Marie Cordero	04 Nov 2020 21:22:51
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint Verified.		16 Apr 2021 17:23:41
User closed query 'per source 11oct2020. please confirm and update if necessary. ' (Site from CRA). User signature succeeded.		16 Apr 2021 17:23:40
	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
	(b) (4)	
Query 'per source 11oct2020. please confirm and update if necessary. ' answered with 'updated to match how the query people and monitors want the eduary responses to be. will include the times since it occurred within 24 hours of getting the second ip dose.' (Site from CRA).	Carrie Kibler (b) (4)	15 Apr 2021 20:38:32
	(b) (4)	
User entered '10 Oct 2020' reason for change: New Information	Carrie Kibler (b) (4)	15 Apr 2021 20:37:49
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	15 Apr 2021 20:35:40
	(b) (4)	
Signature has been broken.	Carrie Kibler (b) (4)	15 Apr 2021 20:35:40
	(b) (4)	
User entered '11 Oct 2020' reason for change: New Information	Carrie Kibler (b) (4)	15 Apr 2021 20:35:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:01:48
User opened query 'per source 11oct2020. please confirm and update if necessary. ' (Site from CRA). User signature succeeded.		14 Apr 2021 16:01:44
	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
	(b) (4)	
User entered '11 Nov 2020' reason for change: New Information	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:35:54
User entered '5 Nov 2020' reason for change: Data Entry Error	Thea Marie Cordero	06 Nov 2020 16:13:48
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:22:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint Verified.		16 Apr 2021 17:23:44
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Apr 2021 20:40:41
User entered '22:10' reason for change: New Information	System	15 Apr 2021 20:40:41
User opened query 'Data is required. Please provide.' (Site from System).	Carrie Kibler (b) (4)	15 Apr 2021 20:40:41
DataPoint Un-verified.	(b) (4)	15 Apr 2021 20:37:49
Signature has been broken.	Carrie Kibler (b) (4)	15 Apr 2021 20:35:40
User entered empty; reason for change New Information	(b) (4)	15 Apr 2021 20:35:40
DataPoint Verified.	Carrie Kibler (b) (4)	14 Apr 2021 16:01:52
User signature succeeded.	(b) (4), (b) (6)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	Thea Marie Cordero (b) (4)	22 Mar 2021 15:16:54
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'refer to ed diary for time.' (Site from System).	(b) (4), (b) (6)	04 Feb 2021 17:07:08
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	Carrie Kibler (b) (4)	02 Feb 2021 21:30:11
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:29:06
User entered '12:01' reason for change: New Information	System	02 Feb 2021 21:29:06
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
DataPoint inactivated with code reason code Data not required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint Verified.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
	(b) (4)	19 Jan 2021 21:35:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 21:22:51

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User entered '10 Oct 2020 22:10'	System	15 Apr 2021 20:40:41
User entered empty.	System	15 Apr 2021 20:35:40
User entered '11 Nov 2020 12:01'	System	02 Feb 2021 21:29:06
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
User entered empty.	System	04 Nov 2020 21:22:51

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:36:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:36:02
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:36:05
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 21:22:51

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:36:07
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:50:43
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 21:22:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:50:45
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:50:46
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 21:22:51

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:50:50
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:22:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:50:49
User entered empty.	Thea Marie Cordero	04 Nov 2020 21:22:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:01
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:02
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:04
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint Verified.		14 Apr 2021 16:01:58
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
	(b) (4)	
DataPoint Un-verified.	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
	(b) (4)	
User entered 'Related (RELATED)' reason for change: New Information	Carrie Kibler (b) (4)	02 Feb 2021 21:29:06
	(b) (4)	
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 21:59:10
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	04 Nov 2020 21:22:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:12
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:13
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:15
User entered '1'	Thea Marie Cordero	04 Nov 2020 21:22:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:16
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 21:22:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:18
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 16:13:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	04 Nov 2020 21:22:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:20
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 21:22:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:16:54
DataPoint activated with code reason code Data required.	(b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
DataPoint Verified.	(b) (4)	19 Jan 2021 21:59:22
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 21:22:51
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	02 Feb 2021 21:11:41
User entered '0'	System	04 Nov 2020 21:22:51

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
User entered '0'	System	02 Feb 2021 21:29:06
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41
User entered '1'	System	02 Feb 2021 21:03:09
User entered '0'	System	04 Nov 2020 21:22:51

US3862128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:06:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:55
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	02 Feb 2021 21:28:00
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	02 Feb 2021 21:11:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:10:47
User entered 'USA-US121-2021-mRNA-1273-P301000008'	System	29 Apr 2021 13:10:43
User entered 'New'	(b) (4), (b) (6)	29 Apr 2021 13:10:43

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 19:45:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Apr 2021 19:45:31
Data point term sent to Coder	System	28 Apr 2021 19:40:32
User entered 'DIVERTICULITIS'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Apr 2021'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered '1'	System	28 Apr 2021 19:40:30
	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Apr 2021'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Narrative](#)

Audit	User	Time (GMT)
User entered '70 y/o female with PMH of diverticulosis since 2016 presented to the Memorial Hermann satellite ER clinics in Humble on 26 Apr 2021 with severe abdominal pain, nausea and vomiting. The participant started having lower abdominal pain (felt like bladder spasm) on 25 Apr 2021 followed by nausea and vomiting (QH30-40 min). By midafternoon on 26 Apr 2021 the abdominal pain increased in severity (10/10) and was generalized in location. While in ER she received IV fluid, Morphine for pain and Ondansetron for nausea. She had a CT of the abdomen and pelvis which identified diverticulitis in the sigmoid colon. Previous colonoscopy done in the Fall 2020 indicated diverticula in the colon. She was transferred to Memorial Hermann NE where she was admitted for treatment and monitoring. Per participant' statement she will be discharged on 29 Apr 2021. Medical records will be requested upon the participant's discharge.' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 19:55:38
User entered empty.	(b) (4), (b) (6)	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 19:40:30

US3862128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:06:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 19:40:30

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:06:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:35:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:29
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 20:35:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:02
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: LETROZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:24:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:24:51
Data point term sent to Coder	System	08 Sep 2020 21:24:06
User entered 'Letrozole'	Trent Davis (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:04
User entered 'No (N)'	(b) (4), (b) (6)	
	Trent Davis (b) (4)	08 Sep 2020 21:23:08
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:05
User entered 'Breast Cancer'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:32:07
User entered '2.5'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:32:08
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:32:10
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:11
User entered 'once daily (QD)'	(b) (4), (b) (6)	
	Trent Davis (b) (4)	08 Sep 2020 21:23:08
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:13
User entered empty.	(b) (4), (b) (6)	
	Trent Davis (b) (4)	08 Sep 2020 21:23:08
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:32:17
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:19
User entered 'un UNK 2017'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:20
User entered '0'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:21
User entered 'Yes (Y)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:32:22
User entered empty.	(b) (4), (b) (6)	
	Trent Davis (b) (4)	08 Sep 2020 21:23:08
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:32:24
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 21:23:08

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:32:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:32:59
Data point term sent to Coder	System	08 Sep 2020 21:31:32
User entered 'Synthroid'	Trent Davis (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:37:20
User entered 'No (N)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 18:37:22
User entered 'HYpothyroidism'	Trent Davis (b) (4)	08 Sep 2020 21:31:17
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:24
User entered '112'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	19 Jan 2021 22:00:07
DataPoint Un-verified.	(b) (4), (b) (6)	
	Shetel Anassi (b) (4)	28 Oct 2020 20:49:54
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:49:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:25
User entered 'Other (OTHER)'	Trent Davis (b) (4)	08 Sep 2020 21:31:17
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:00:09
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:06:08
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4)	28 Oct 2020 20:50:03
DataPoint Un-verified.	Shetel Anassi (b) (4)	28 Oct 2020 20:49:54
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:49:54
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:38:22
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:27
User entered 'mcg'	Trent Davis (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:37:29
User entered 'once daily (QD)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:30
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:32
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:34
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User closed query 'Per source, start date is un/unk/1987. Please update edc accordingly. ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 15:18:13
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:18:10
Query 'Per source, start date is un/unk/1987. Please update edc accordingly. ' answered with 'Data corrected' (Site from CRA).	Shetel Anassi (b) (4)	28 Oct 2020 20:50:18
	(b) (4)	
User entered 'un UNK 1987' reason for change: Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:50:11
	(b) (4)	
User opened query 'Per source, start date is un/unk/1987. Please update edc accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:37:09
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).		08 Sep 2020 21:31:26
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Sep 2020 21:31:17
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:31:17
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	06 Nov 2020 15:18:15
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	28 Oct 2020 20:50:21
User entered '0' reason for change: Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:50:21
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	28 Oct 2020 20:50:11
User entered '1' reason for change: Data Entry Error	Trent Davis (b) (4)	08 Sep 2020 21:31:26
User entered '0'	Trent Davis (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:11
User entered 'Yes (Y)'	Trent Davis (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:14
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:16
User entered 'No (N)'	Trent Davis (b) (4)	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 21:31:17

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:41:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:33:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:33:50
Data point term sent to Coder User entered 'Rosuvastatin'	System Trent Davis (b) (4)	08 Sep 2020 21:32:35 08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:48
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:47
User entered 'Elevated Cholesterol'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:41:45
User entered '5'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:41
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:41:36
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:41:34
User entered 'once daily (QD)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:33
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:41:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:29
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User closed query 'Per source, start date is un/unk/2014. Please update edc accordingly. ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 15:18:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:18:21
Query 'Per source, start date is un/unk/2014. Please update edc accordingly. ' answered with 'Data corrected' (Site from CRA).	Shetel Anassi (b) (4)	28 Oct 2020 20:50:45
User entered 'un UNK 2014' reason for change: Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:50:37
User opened query 'Per source, start date is un/unk/2014. Please update edc accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:42:36
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	06 Nov 2020 15:18:28
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	28 Oct 2020 20:50:48
User entered '0' reason for change: Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:50:48
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	28 Oct 2020 20:50:37
User entered '1'	Trent Davis (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:26
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:41:24
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:23
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 21:32:20

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, PRODUCT: ACETAZOLAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 21:33:33
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 21:33:33
	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 20:58:28
Coding entries removed.	Carrie Kibler (b) (4)	02 Feb 2021 20:57:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:48:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: ACETAZOLAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:59:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 23:59:03
	(b) (4)	
Data point term sent to Coder	System	08 Sep 2020 21:34:41
User entered 'Acetazolamide'	Trent Davis (b) (4)	08 Sep 2020 21:34:01
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:04:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User closed query 'Per DM CLR: Prophylaxis = YES, however, there is a corresponding MedHistory condition that matches the ConMed's indication. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 17:07:51
Query 'Per DM CLR: Prophylaxis = YES, however, there is a corresponding MedHistory condition that matches the ConMed's indication. Please confirm and update as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Carrie Kibler (b) (4)	02 Feb 2021 20:57:44
DataPoint Un-verified.	Carrie Kibler (b) (4)	02 Feb 2021 20:57:05
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Feb 2021 20:57:05
User opened query 'Per DM CLR: Prophylaxis = YES, however, there is a corresponding MedHistory condition that matches the ConMed's indication. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:17:20
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:48:13
User entered 'Yes (Y)'	Trent Davis (b) (4)	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:04:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Un-verified.	(b) (4)	02 Feb 2021 20:57:39
User entered 'ALTITUDE SICKNESS' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Feb 2021 20:57:39
DataPoint Verified.	(b) (4)	09 Nov 2020 22:53:28
User closed query 'Please add Altitude Sickness to MH in edc, as subject is taking medication for it on a prn basis.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:53:00
Query 'Please add Altitude Sickness to MH in edc, as subject is taking medication for it on a prn basis.' answered with 'data corrected' (Site from CRA).	Shetel Anassi (b) (4)	28 Oct 2020 20:51:44
User opened query 'Please add Altitude Sickness to MH in edc, as subject is taking medication for it on a prn basis.' (Site from CRA).	(b) (4)	14 Oct 2020 18:48:09
User entered 'Prophylaxis for altitude sickness'	(b) (4), (b) (6)	08 Sep 2020 21:34:01
	Trent Davis (b) (4)	
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:48:14
User entered '125'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:48:16
User entered 'mg (mg)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:48:18
User entered empty.	(b) (4), (b) (6)	
	Trent Davis (b) (4)	08 Sep 2020 21:34:01
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:48:20
User entered 'as needed (PRN)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:48:21
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 18:48:24
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	08 Sep 2020 21:34:01
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:48:26
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User closed query 'Per source, start date is un/unk/2008. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 15:18:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:18:45
Query 'Per source, start date is un/unk/2008. Please update EDC accordingly. ' answered with 'data corrected' (Site from CRA).	Shetel Anassi (b) (4)	28 Oct 2020 20:51:38
User entered 'un UNK 2008' reason for change: Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:51:30
User opened query 'Per source, start date is un/unk/2008. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:49:06
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:48:30
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:48:27
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:18:50
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	28 Oct 2020 20:51:47
User entered '0' reason for change: Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:51:47
	(b) (4)	
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	28 Oct 2020 20:51:30
User entered '1'	Trent Davis (b) (4)	08 Sep 2020 21:34:01
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:48:32
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:48:33
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 18:48:34
User entered 'No (N)'	Trent Davis (b) (4)	08 Sep 2020 21:34:01
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 21:34:01

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:49:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:53:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:53:15
Data point term sent to Coder Coding entries removed.	System Trent Davis (b) (4)	08 Sep 2020 21:48:08 08 Sep 2020 21:47:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:45:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 21:45:03
Data point term sent to Coder User entered 'Vitamin D3'	System Trent Davis (b) (4)	08 Sep 2020 21:44:03 08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:49:19
User entered 'No (N)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:49:20
User entered 'Osteopenia'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:21
User entered '1000'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:23
User entered 'IU (IU)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:49:25
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:49:26
User entered 'once daily (QD)'	Trent Davis (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:49:33
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:49:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 21:47:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 21:47:30
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Trent Davis (b) (4)	08 Sep 2020 21:47:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 21:43:12
User entered empty.	System	08 Sep 2020 21:43:12
	Trent Davis (b) (4)	08 Sep 2020 21:43:12
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:31
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:49:29
User entered 'un UNK 2017'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:49:35
User entered '0'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:49:36
User entered 'Yes (Y)'	Trent Davis (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:38
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:49:40
User entered 'No (N)'	Trent Davis (b) (4)	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 21:43:12

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:50:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 13:55:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 13:55:05
Data point term sent to Coder	System	13 Oct 2020 23:49:16
Coding entries removed.	Chanei Henry (b) (4)	13 Oct 2020 23:49:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 22:01:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 22:01:48
Data point term sent to Coder	System	08 Sep 2020 22:00:34
User entered 'Vitamin B12'	Trent Davis (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:09
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User closed query 'Per CDM: Indication is recorded as "Prophylaxis". Please update the indication of this medication to also include the medical condition/ diagnosis which needed this ConMed (Like: Preventative Heart Disease/ UTI/ Pregnancy).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:33:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:50:11
Query 'Per CDM: Indication is recorded as "Prophylaxis". Please update the indication of this medication to also include the medical condition/ diagnosis which needed this ConMed (Like: Preventative Heart Disease/ UTI/ Pregnancy).' answered with 'indication updated' (Site from DM).	Chanei Henry (b) (4)	13 Oct 2020 23:49:26
User entered 'PROPHYLAXIS for good health' reason for change: Per Query Resolution	(b) (4)	13 Oct 2020 23:49:15
User opened query 'Per CDM: Indication is recorded as "Prophylaxis". Please update the indication of this medication to also include the medical condition/ diagnosis which needed this ConMed (Like: Preventative Heart Disease/ UTI/ Pregnancy).' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:25:25
User entered 'Prophylaxis'	Trent Davis (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:50:14
User entered '500'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 22:00:32
DataPoint Un-verified.	Shetel Anassi (b) (4)	28 Oct 2020 20:55:01
User entered 'ug (ug)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:55:01
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:50:17
User entered 'Other (OTHER)'	Trent Davis (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 22:00:33
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).		03 Nov 2020 13:06:40
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4)	28 Oct 2020 20:55:09
DataPoint Un-verified.	(b) (4)	
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4)	28 Oct 2020 20:55:01
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:38:37
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:50:19
User entered 'mcg'	Trent Davis (b) (4)	08 Sep 2020 22:00:24
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:50:21
User entered 'once daily (QD)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:23
User entered empty.	Trent Davis (b) (4) (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:50:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:50:29
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:32
User entered 'un May 2020'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:50:34
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	08 Sep 2020 22:00:41
User entered '0' reason for change: Data Entry Error	Trent Davis (b) (4)	08 Sep 2020 22:00:41
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	08 Sep 2020 22:00:24
User entered '1'	Trent Davis (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:36
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:50:38
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:50:39
User entered 'No (N)'	(b) (4), (b) (6)	
	Trent Davis (b) (4)	08 Sep 2020 22:00:24
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:00:24

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 18:51:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 22:14:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 22:14:52
Data point term sent to Coder	System	08 Sep 2020 22:14:15
User entered 'Calcium'	Trent Davis (b) (4)	08 Sep 2020 22:13:58
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 18:51:19
User entered 'No (N)'	Trent Davis (b) (4)	08 Sep 2020 22:13:58
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:51:20
User entered 'Osteopenia'	(b) (4), (b) (6)	
	Trent Davis (b) (4)	08 Sep 2020 22:13:58
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
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)	16 Apr 2021 13:12:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:06:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
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 'data correction done in EDC and source doc' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 23:26:57
User entered '1500' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 23:26:19
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)	25 Feb 2021 19:32:52
DataPoint Un-verified.	Carrie Kibler (b) (4)	02 Feb 2021 21:49:53
User entered '1' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Feb 2021 21:49:53
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:51:27
User entered 'unknown'	Trent Davis (b) (4)	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:06:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	23 Mar 2021 23:26:19
DataPoint Un-verified.	(b) (4), (b) (6)	
	Carrie Kibler (b) (4)	02 Feb 2021 21:49:53
User entered 'tablet (TABLET)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	02 Feb 2021 21:49:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 18:51:27
User entered 'Other (OTHER)'	(b) (4)	
	Trent Davis (b) (4)	08 Sep 2020 22:13:58
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:06:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:49:53
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	02 Feb 2021 21:49:53
DataPoint Verified.	(b) (4)	14 Oct 2020 18:51:27
User entered 'unknown'	Trent Davis (b) (4)	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:51:27
User entered 'once daily (QD)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:51:27
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:51:27
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:51:27
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:51:27
User entered 'un UNK 2017'	(b) (4), (b) (6)	
	Trent Davis (b) (4)	08 Sep 2020 22:13:58
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:51:27
User entered '0'	(b) (4), (b) (6)	
	Trent Davis (b) (4)	08 Sep 2020 22:13:58
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:51:27
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:51:27
User entered empty.	Trent Davis (b) (4)	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:51:27
User entered 'No (N)'	Trent Davis (b) (4)	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 22:13:58

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:52:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: PSYLLIUM HYDROPHILIC MUCILLOID, PRODUCTSYNONYM: METAMUCIL [PSYLLIUM HYDROPHILIC MUCILLOID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 06:21:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 06:21:52
Data point term sent to Coder	System	16 Sep 2020 23:26:31
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	16 Sep 2020 23:25:47
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'active ingredient added' (Site from System).	Chanei Henry (b) (4)	16 Sep 2020 23:25:47
User entered 'METAMUCIL [psyllium fiber]' reason for change: Data Entry Error	Chanei Henry (b) (4)	16 Sep 2020 23:25:37
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	14 Sep 2020 11:58:38
Data point term sent to Coder	System	09 Sep 2020 15:37:10
User entered 'Metamucil'	Trent Davis (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:52:02
User entered 'Irritable Bowel Disease'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:52:02
User entered '2'	(b) (4), (b) (6)	
	Trent Davis (b) (4)	09 Sep 2020 15:36:55
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered 'capsule (CAPSULE)'	Trent Davis (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered empty.	Trent Davis (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered 'once daily (QD)'	Trent Davis (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:52:02
User entered empty.	(b) (4), (b) (6)	
	Trent Davis (b) (4)	09 Sep 2020 15:36:55
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 18:52:02
User entered empty.	(b) (4), (b) (6)	
	Trent Davis (b) (4)	09 Sep 2020 15:36:55
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered 'un UNK 2020'	Trent Davis (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered '0'	Trent Davis (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered empty.	Trent Davis (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:52:02
User entered 'No (N)'	Trent Davis (b) (4)	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 15:36:55

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:58:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:58:56
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 22:55:04
Coding entries removed.	Chanei Henry (b) (4)	13 Nov 2020 22:54:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:03:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 16:14:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 16:14:44
	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 15:50:47
Data point term sent to Coder	System	09 Sep 2020 15:39:20
User entered 'Denosumab'	Trent Davis (b) (4)	09 Sep 2020 15:39:16
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 19:03:25
User entered 'No (N)'	(b) (4), (b) (6)	
	Trent Davis (b) (4)	09 Sep 2020 15:39:16
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:03:27
User entered 'Osteopenia'	Trent Davis (b) (4)	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:07:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Un-verified.	(b) (4)	
	Sandra Francisco (b) (4)	22 Feb 2021 22:49:14
User entered '60' reason for change: New Information	(b) (4)	
	Sandra Francisco (b) (4)	22 Feb 2021 22:49:14
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:03:28
User entered 'unknown'	Trent Davis (b) (4)	09 Sep 2020 15:39:16
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:07:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Un-verified.	(b) (4)	
	Sandra Francisco (b) (4)	22 Feb 2021 22:49:14
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Sandra Francisco (b) (4)	22 Feb 2021 22:49:14
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:03:30
User entered 'Other (OTHER)'	Trent Davis (b) (4)	09 Sep 2020 15:39:16
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:07:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Un-verified.	(b) (4)	
	Sandra Francisco (b) (4)	22 Feb 2021 22:49:14
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sandra Francisco (b) (4)	22 Feb 2021 22:49:14
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:03:32
User entered 'unknown'	Trent Davis (b) (4)	09 Sep 2020 15:39:16
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:03:34
User entered 'other (OTHER)'	Trent Davis (b) (4)	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 19:03:37
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	
	System	09 Sep 2020 16:10:21
User entered 'every 6 months' reason for change: Data Entry Error	Trent Davis (b) (4)	09 Sep 2020 16:10:21
	(b) (4)	
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	09 Sep 2020 15:39:16
User entered empty.	Trent Davis (b) (4)	09 Sep 2020 15:39:16
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:07:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 09:17:12
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'route corrected' (Site from DM).	Chanei Henry (b) (4) (b) (4)	13 Nov 2020 22:54:31
DataPoint Un-verified.	Chanei Henry (b) (4) (b) (4)	13 Nov 2020 22:54:14
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Chanei Henry (b) (4) (b) (4)	13 Nov 2020 22:54:14
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 09:34:50
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:03:40
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 15:50:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 15:50:42
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:50:42
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 15:39:16
User entered empty.	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:03:54
User entered empty.	Trent Davis (b) (4)	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:07:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Un-verified.	(b) (4)	02 Feb 2021 21:51:29
User entered 'UN UNK 2019' reason for change:	Carrie Kibler (b) (4)	02 Feb 2021 21:51:29
Data Entry Error	(b) (4)	02 Feb 2021 21:51:29
User closed query 'Per source, start date is un/unk/2017. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 15:19:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:19:17
Query 'Per source, start date is un/unk/2017. Please update EDC accordingly. ' answered with 'data corrected' (Site from CRA).	Shetel Anassi (b) (4)	28 Oct 2020 20:56:08
User entered 'un UNK 2017' reason for change:	(b) (4)	28 Oct 2020 20:56:01
Data Entry Error	(b) (4)	14 Oct 2020 19:03:21
User opened query 'Per source, start date is un/unk/2017. Please update EDC accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 19:03:21
User entered empty.	Trent Davis (b) (4)	09 Sep 2020 15:39:16
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:19:23
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	28 Oct 2020 20:56:13
User entered '0' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	28 Oct 2020 20:56:13
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	28 Oct 2020 20:56:01
User entered '1'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 19:03:58
User entered 'Yes (Y)'	(b) (4), (b) (6) Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:04:00
User entered empty.	Trent Davis (b) (4)	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:04:01
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:39:16

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
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)	31 Mar 2021 19:46:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 19:46:09
Data point term sent to Coder Coding entries removed.	System Carrie Kibler (b) (4)	31 Mar 2021 19:45:01 31 Mar 2021 19:44:57
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)	29 Oct 2020 20:07:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 20:07:41
Data point term sent to Coder Coding entries removed.	System Shetel Anassi (b) (4)	28 Oct 2020 20:57:06 28 Oct 2020 20:56:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:07:03
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)	13 Oct 2020 23:54:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Oct 2020 23:54:19
Data point term sent to Coder	System	13 Oct 2020 23:53:20
Data point term sent to Coder	System	13 Oct 2020 23:52:19
User entered 'Tylenol'	Chanei Henry (b) (4)	13 Oct 2020 23:51:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4)	14 Oct 2020 19:07:05
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 19:07:05
	Chanei Henry (b) (4)	13 Oct 2020 23:51:28
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
DataPoint Verified.		14 Apr 2021 16:08:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Un-verified.	(b) (4) Carrie Kibler (b) (4)	31 Mar 2021 19:44:57
User entered 'solicited symptoms: low grade FEVER, pain' reason for change: New Information DataPoint Verified.	(b) (4) Carrie Kibler (b) (4) (b) (4), (b) (6)	31 Mar 2021 19:44:57 08 Dec 2020 18:21:54
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, PAIN 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 FEVER, PAIN did not meet the AE reporting criteria.' (Site from DM).		07 Dec 2020 12:56:15
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:56:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, PAIN 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 FEVER, PAIN did not meet the AE reporting criteria.' answered with 'per protocol AE not needed this is a solicited reaction that did result in a visit to a healthcare provider, lead to withdrawal from the study of study vaccination, or meet the definition of an SAE' (Site from DM).	Trent Davis (b) (4)	04 Dec 2020 19:10:20
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'data is correct' (Site from DM).	Trent Davis (b) (4)	04 Dec 2020 18:54:42
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, PAIN 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 FEVER, PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 18:53:23
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 18:52:58

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per eCRF guidelines, please list primary indication and update EDC and source. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:54:45
Query 'Per eCRF guidelines, please list primary indication and update EDC and source. ' answered with 'Data corrected' (Site from CRA).	Shetel Anassi (b) (4)	28 Oct 2020 20:56:45
User entered 'FEVER' reason for change: New Information	(b) (4)	28 Oct 2020 20:56:38
User opened query 'Per eCRF guidelines, please list primary indication and update EDC and source. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 19:07:02
User entered 'FEVER, Pain' reason for change: New Information	Chanei Henry (b) (4)	13 Oct 2020 23:52:50
User entered 'fever'	Chanei Henry (b) (4)	13 Oct 2020 23:51:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:07:08
User entered '1000'	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:07:13
User entered 'mg (mg)'	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:07:15
User entered empty.	Chanei Henry (b) (4)	13 Oct 2020 23:51:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:11:49
User entered 'three times daily (TID)'	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:11:50
User entered empty.	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:11:52
User entered 'Oral (ORAL)'	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:11:55
User entered empty.	Chanei Henry (b) (4)	13 Oct 2020 23:51:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
DataPoint Verified.		14 Apr 2021 16:08:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	31 Mar 2021 19:44:57
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 19:44:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:59
User entered '3 Oct 2020'	Chanei Henry (b) (4)	13 Oct 2020 23:51:28
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:12:05
User entered '0'	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:12:06
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
DataPoint Verified.		14 Apr 2021 16:08:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Un-verified.	(b) (4)	
	Carrie Kibler (b) (4)	31 Mar 2021 19:44:57
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 19:44:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:12:07
User entered '3 Oct 2020'	Chanei Henry (b) (4)	13 Oct 2020 23:51:28
	(b) (4)	

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:12:09
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User entered '3'	System	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User entered '1'	System	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:06:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:49:26
User entered '804 (804)'	System	13 Oct 2020 23:51:28

US3862128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:06:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:29:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 23:23:40

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered 'Visit 3 Day 57 (VISIT3)'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '1'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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Central Laboratory - Nasopharyngeal Swab

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

US3862128

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '1'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Form: COVID-19 Impact (1)

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[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '1'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '1'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '1'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

US3862128

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:06:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 19:06:51
User entered '2 Nov 2020' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:51
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 19:06:29
User entered empty.	Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

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[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

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[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

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[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '1'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

US3862128

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered 'ILLNESS VISIT'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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Folder: COVID-19 Impact (1)

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[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Form: COVID-19 Impact (1)

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[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

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[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '1'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
	(b) (4)	
User entered '0'	Thea Marie Cordero	12 Nov 2020 19:06:29
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 10:06:48

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:21
DataPoint Verified.		14 Apr 2021 17:29:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:25:08
User entered '0'	(b) (4) Thea Marie Cordero (b) (4)	12 Nov 2020 19:06:29

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'USA-US121-2021-MRNA-1273-P301000008'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'Yes (Y)'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'No (N)'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'No (N)'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'Yes (Y)'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4)	29 Apr 2021 13:11:08
User entered 'No (N)'	(b) (4), (b) (6) System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'No (N)'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'No (N)'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'Thea Marie'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'Cordero'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'Houston'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'TX'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4)	29 Apr 2021 13:11:08
User entered '77030'	(b) (4), (b) (6) System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
	(b) (4)	
User entered 'US'	System	29 Apr 2021 13:11:36

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:11:36

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'USA-US121-2021-MRNA-1273-P301000008'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4)	29 Apr 2021 13:11:08
User entered 'Yes (Y)'	(b) (4), (b) (6) System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4)	29 Apr 2021 13:11:08
User entered 'No (N)'	(b) (4), (b) (6) System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'No (N)'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'Yes (Y)'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4)	29 Apr 2021 13:11:08
User entered 'No (N)'	(b) (4), (b) (6) System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'No (N)'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4)	29 Apr 2021 13:11:08
User entered 'No (N)'	(b) (4), (b) (6) System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'Thea Marie'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4)	29 Apr 2021 13:11:08
User entered 'Cordero'	(b) (4), (b) (6) System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'Houston'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered 'TX'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:08
User entered '77030'	System	29 Apr 2021 13:10:43

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
	(b) (4)	
User entered 'US'	System	29 Apr 2021 13:11:36

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 10:06:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:11:36

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:06:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
	(b) (4)	
User entered '29/Apr/2021 06:11'	System	29 Apr 2021 13:11:36

US3862128

Folder: SAE USA-US121-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:06:48

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)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:14
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Apr 2021 13:11:36
User entered '0'		29 Apr 2021 13:11:27