

US3382284 (Prod: Advanced Clinical Research – Be Well MD - ERN - PPDS)

Generated By: KC Joubran

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US3382284

Form: Participant Creation

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

[Participant ID](#)

US3382284

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

US3382284

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 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) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
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) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Date of Informed Consent (dd MMM yyyy)	16 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) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	08:57 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:57
Height (xxx.x)	67 in
Weight (xxx.x)	157.2 lb
BMI (xxx.x)	24.67248 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 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: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 17:27:37

Generated On: 09 Jun 2021 17:20:00

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

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) 23 Feb 2021 17:27:37

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 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) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

What was the date of randomization? (dd MMM yyyy) 16 SEP 2020

What was the participant's randomization number? 113974

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) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

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) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	08:57 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:57
Temperature (xxx.x)	96.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:45
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 16 SEP 2020

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 10:15

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) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	16 SEP 2020
Collection time (00:00-23:59)	09:32 (24 HR)
Collection date and time (derived)	16 SEP 2020 09:32

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:40	16 SEP 2020 09:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

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: 09 Jun 2021 17:20:00

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

16 SEP 2020 10:48

PC Open Date & Time

16 SEP 2020 10:35

PC Close Date & Time

16 SEP 2020 13:05

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp	17 SEP 2020 11:54
PC Open Date & Time	16 SEP 2020 14:00
PC Close Date & Time	17 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

18 SEP 2020 13:30

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

21 SEP 2020 12:33

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

23 SEP 2020 09:35

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 10:49

PC Open Date & Time

16 SEP 2020 10:35

PC Close Date & Time

16 SEP 2020 13:05

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

Please record - **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

17 SEP 2020 11:55

PC Open Date & Time

16 SEP 2020 14:00

PC Close Date & Time

17 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 13:31

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 12:34

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 09:36

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 10:49
PC Open Date & Time	16 SEP 2020 10:35
PC Close Date & Time	16 SEP 2020 13:05

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 11:55
PC Open Date & Time	16 SEP 2020 14:00
PC Close Date & Time	17 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

Yes ☐

PC Time stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

Yes ☐	
PC Time stamp	18 SEP 2020 13:31
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

Yes ☐

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

Yes ☐

PC Time stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 844

EAB) (1725)

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

Yes ☐	
PC Time stamp	21 SEP 2020 12:34
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 844

EAB) (1725)

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

Yes ☐	
PC Time stamp	23 SEP 2020 09:36
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

24 SEP 2020 11:45

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 25 SEP 2020 09:59

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

26 SEP 2020 16:47

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	24 SEP 2020 11:45
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	25 SEP 2020 09:59
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	26 SEP 2020 16:47
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3382284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382284

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3382284

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3382284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3382284

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:01:08

Generated On: 09 Jun 2021 17:20:00

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

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 ☐

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3382284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:20:00

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

US3382284

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:20:00

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

US3382284

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:20:00

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3382284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:20:00

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 _____

US3382284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:20:00

Date of updated informed consent (<i>dd MMM yyyy</i>)		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
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 (<i>dd MMM yyyy</i>)		
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		

US3382284

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:20:00

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3382284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:20:00

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00 - 23:59</i>)	
Collection Date and Time (derived)	

US3382284

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Mar 2021 17:12:42

Generated On: 09 Jun 2021 17:20:00

AEID	
Adverse event	FATIGUE
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)	23 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	25 SEP 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)

Data signed: (b) (4) 09 Mar 2021 17:12:42

Generated On: 09 Jun 2021 17:20:00

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)	

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 17:12:42

Generated On: 09 Jun 2021 17:20:00

AEID USA-US096-2020-MRNA-1273-P30
1000003

Adverse event GASTRIC CANCER

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) 29 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)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☒
Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 17:12:42

Generated On: 09 Jun 2021 17:20:00

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 17:12:42

Generated On: 09 Jun 2021 17:20:00

06-OCT-2020: LEFT EPIGASTRIC
DULL, CONSTANT, 7/10
NON-RADIATING PAIN BEGINS.
NO OTHER SYMPTOMS AT THIS
TIME.

12-OCT-2020: PCP ON-SITE
VISIT. SUBJECTS REPORTS
BLOOD TESTS ORDERED TO
CHECK FOR H.PYLORI.

13-OCT-2020: SUBJECT CALLED
RECEIVES RESULTS. INFORMED
IT'S A GASTRIC ULCER.

17-OCT-2020: SUBJECT VISITS
ER AT UNIVERSITY HOSPITAL
SAN ANTONIO DUE TO PAIN
NOW RADIATING TO LEFT
FLANK. SUBJECT REPORTS
NEWLY NOTICED WEIGHT
LOSS AT THIS TIME.

DISCHARGED AND REFERRED
TO GI FOR ENDOSCOPY W/
BIOPSY.

22-OCT-2020: ENDOSCOPY W/
BIOPSY PERFORMED

29-OCT-2020: GIVEN DIAGNOSIS
OF STAGE 1 GASTRIC CANCER.
APPOINTMENT MADE WITH
ONCOLOGIST FOR 08-DEC-2020.

31-OCT-2020: SUBJECT
RETURNS TO ER DUE TO NOW
10/10 PAIN WITH RADIATION TO
LEFT FLANK. CT SCAN DONE.
RESULT: STAGE 1-2 GASTRIC
CANCER
(SUBMUCOSAL/MUSCLE

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 17:12:42

Generated On: 09 Jun 2021 17:20:00

INVASION). SWITCHED FROM
MEDICATION PRESCRIBED AT
PREVIOUS ER VISIT
(SUCRALFATE) TO
OMEPRAZOLE. WAITING FOR
SUBJECT TO CALL BACK FOR
MEDICATION DOSAGE DETAILS
AS HE WAS AT WORK AND
COULDN'T TALK FOR LONG.
TOLD TO SEE PCP FOR
CARDIOLOGIST REFERRAL AS
THERE'S AFFECTATION OF AN
ARTERY WITH CLOSE
PROXIMITY TO THE HEART.
NOTE: SUBJECT ISN'T ABLE TO
SEE PCP OR CARDIOLOGIST
FOR FOLLOW-UP AS THEY
DON'T HAVE INSURANCE.
WORKING ON GETTING THAT
SITUATED.

NOTE: DIAGNOSIS MADE
29-OCT-2020, BUT SITE
NOTIFIED TODAY 06-NOV-2020.

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

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Mar 2021 17:12:42

Generated On: 09 Jun 2021 17:20:00

AEID

Adverse event

ABDOMINAL PAIN

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)

06 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)

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 (3)

Data signed: (b) (4) 09 Mar 2021 17:12:42

Generated On: 09 Jun 2021 17:20:00

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

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

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

Yes ☒

No ☐

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

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

Name of Medication MORPHINE, EXTENDED
RELEASE

Prophylaxis Yes ☐
No ☒

Indication GASTRIC CANCER

Dose per administration 15

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 Q12H

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

Name of Medication SULCRAFATE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN/GASTRIC
CANCER

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 ☐

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN/GASTRIC
CANCER

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Mar 2021 17:12:42

Generated On: 09 Jun 2021 17:20:00

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 OCT 2020	ENDOSCOPY WITH BIOPSIES	Adverse Event	
31 OCT 2020	CT SCAN ABDOMEN	Adverse Event	
12 OCT 2020	HELICOBACTER PYLORI BLOOD TEST	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

Date of dosing discontinuation (dd MMM yyyy) 20 NOV 2020

Primary reason for dosing discontinuation

AE (specify)	☐
SAE (specify)	☒
Death	☐
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Due to SARS-COV-2	☐
Other	☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

AE #2

US3382284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 26 Jan 2021 20:01:07

Generated On: 09 Jun 2021 17:20:00

Date of study discontinuation/completion (dd MMM yyyy) 20 NOV 2020

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 AE#2 (SAE) SUBJECT WITHDREW CONSENT

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	☐

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 04 Feb 2021 18:29:08

Generated On: 09 Jun 2021 17:20:00

SAEID	USA-US096-2020-MRNA-1273-P301000003
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	SINIKKA
Investigator's Last Name	GREEN
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 04 Feb 2021 18:29:08

Generated On: 09 Jun 2021 17:20:00

SAEID	USA-US096-2020-MRNA-1273-P301000003
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	SINIKKA
Investigator's Last Name	GREEN
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/NOV/2020 19:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 04 Feb 2021 18:29:08

Generated On: 09 Jun 2021 17:20:00

SAEID	USA-US096-2020-MRNA-1273-P301000003
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	SINIKKA
Investigator's Last Name	GREEN
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/DEC/2020 13:19
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

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 04 Feb 2021 18:29:08

Generated On: 09 Jun 2021 17:20:00

SAEID	USA-US096-2020-MRNA-1273-P301000003
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	SINIKKA
Investigator's Last Name	GREEN
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/JAN/2021 15:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 04 Feb 2021 18:29:08

Generated On: 09 Jun 2021 17:20:00

SAEID	USA-US096-2020-MRNA-1273-P301000003
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	SINIKKA
Investigator's Last Name	GREEN
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	04/FEB/2021 07:31
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

US3382284 (Prod: Advanced Clinical Research – Be Well MD - ERN - PPDS)

US3382284

Form: Participant Creation

Generated On: 09 Jun 2021 17:20:00

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		09 Apr 2021 19:28:25
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'US3382284'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	16 Sep 2020 13:49:21

US3382284

Form: Participant Creation

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01

US3382284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:20:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:06:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:38

US3382284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:20:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:06:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	16 Sep 2020 13:49:22

US3382284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:20:00

[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 02:19:11
DataPoint Verified.		03 Feb 2021 17:06:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Clinic (Clinic)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:38

US3382284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:20:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'SCRN'	System	16 Sep 2020 15:40:38

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered (b) (6) 1975'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	16 Sep 2020 13:49:24

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '45'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'YEARS'	System	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '45'	System	16 Sep 2020 15:41:05

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Male (M)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '1'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:20:00

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:32:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:40:53

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:04:49
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '16 Sep 2020'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:05

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'Sep 2020'	System	16 Sep 2020 15:41:05

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '2020'	System	16 Sep 2020 15:41:05

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:04:49
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Amendment 3 (3)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:05

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:04:49
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:05

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:04:49
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:05

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:04:49
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:05

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:04:49
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:05

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:04:49
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	16 Sep 2020 13:49:22

US3382284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:20:00

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '1'	System	16 Sep 2020 15:41:10

US3382284

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:35:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:10

US3382284

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:20:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:38:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:56:48

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 18:56:16
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 18:56:18
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '16 Sep 2020'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 18:56:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '08:57'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '16 Sep 2020 08:57'	System	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 18:56:28
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '67' in	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:49:30
DataPoint set to visible.	System	16 Sep 2020 15:41:10

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 18:56:30
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '157.2' lb	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:49:30
DataPoint set to visible.	System	16 Sep 2020 15:41:10

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '24.67248'	System	07 Oct 2020 19:49:30
DataPoint set to visible.	System	16 Sep 2020 15:41:10

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'kg/m2'	System	07 Oct 2020 19:49:30
DataPoint set to visible.	System	16 Sep 2020 15:41:10

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:48:17
Query 'Per source, temperature and other vital signs (pulse, respiratory rate, BP) were done. Please reconcile.' canceled (Site from CRA).		03 Feb 2021 19:48:12
User opened query 'Per source, temperature and other vital signs (pulse, respiratory rate, BP) were done. Please reconcile.' (Site from CRA).		03 Feb 2021 19:37:13
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 07:29:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:27:31
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:27:13
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	07 Oct 2020 19:49:30
User entered '96.4' F	Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:48:17
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
	(b) (4)	
User entered empty; reason for change Data Entry Error	Michelle Jackson (b) (4)	09 Oct 2020 15:27:31
	(b) (4)	
User entered 'Oral (Oral)'	Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:48:17
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:48:17
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Michelle Jackson (b) (4)	09 Oct 2020 15:27:31
	(b) (4)	
User entered '48'	Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'bpm'	System	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:48:17
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Michelle Jackson (b) (4)	09 Oct 2020 15:27:31
User entered '16'	(b) (4)	
	Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'breaths/min'	System	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:48:17
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Michelle Jackson (b) (4)	09 Oct 2020 15:27:31
User entered '117'	(b) (4)	
	Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'mmHg'	System	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:48:17
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Michelle Jackson (b) (4)	09 Oct 2020 15:27:31
User entered '80'	(b) (4)	
	Triny Cooper (b) (4)	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'mmHg'	System	07 Oct 2020 19:49:30

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11

US3382284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:20:00

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11

US3382284

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:20:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:40:21
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:16

US3382284

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:20:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:40:21
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '16 Sep 2020'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:16

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:44:50
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:44:51
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:44:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:44:55
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:44:56
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:44:58
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:45:01
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:45:02
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:45:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:45:06
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:45:08
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:45:10
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 17:45:14
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:27:37
Signature has been broken.	(b) (4)	17 Feb 2021 16:10:19
Signature has been broken.	Sikhongi Phungwayo	17 Feb 2021 16:10:19
User entered '0' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 16:10:19
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '1'	(b) (4)	07 Oct 2020 19:55:00
	Triny Cooper (b) (4)	

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:24:10
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:24:12
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:24:59
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.	(b) (4)	08 Apr 2021 21:31:36
User signature succeeded.	Sinikka Green (b) (4)	23 Feb 2021 17:27:37
User closed query 'Per source, the subject lives in low density, multi-family setting. Please reconcile, than you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 04:07:26
Query 'Per source, the subject lives in low density, multi-family setting. Please reconcile, than you.' answered with 'reviewed' (Site from CRA).	Sikhongi Phungwayo (b) (4)	17 Feb 2021 16:10:28
Signature has been broken.	Sikhongi Phungwayo (b) (4)	17 Feb 2021 16:10:19
User entered '1' reason for change: Data Entry Error	Sikhongi Phungwayo (b) (4)	17 Feb 2021 16:10:19
User opened query 'Per source, the subject lives in low density, multi-family setting. Please reconcile, than you.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 17:44:44
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 20:01:09
User entered '0'	Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:25:23
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:20:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:25:26
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:55:00

US3382284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:20:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:25:59
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:21

US3382284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:20:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:25:59
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '16 Sep 2020'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:21

US3382284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:20:00

[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 02:19:11
DataPoint Verified.		03 Feb 2021 19:25:59
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Clinic (Clinic)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:21

US3382284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:20:00

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'VISIT1'	System	16 Sep 2020 15:41:21

US3382284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:44:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	16 Sep 2020 14:34:33

US3382284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:44:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '113974'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	16 Sep 2020 14:34:33

US3382284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.	(b) (4)	03 Feb 2021 19:44:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	16 Sep 2020 14:34:33

US3382284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:20:00

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)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:44:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:31

US3382284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:20:00

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)	28 Apr 2021 02:19:11
DataPoint Verified.	(b) (4)	03 Feb 2021 19:44:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:31

US3382284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:44:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:31

US3382284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:20:00

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:44:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:31

US3382284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:20:00

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:44:03
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:31

US3382284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:44:03
User signature succeeded.	(b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:49:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:19:33
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:19:32

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:20:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered missing code ND - Not Done.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:20:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered missing code ND - Not Done.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:20:00

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered missing code ND - Not Done.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:20:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered missing code ND - Not Done.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User accepted default value 'Pre-Dose (PREDOSE)'	Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	(b) (4)	26 Jan 2021 20:01:09
User entered '16 Sep 2020'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '08:57'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '16 Sep 2020 08:57'	System	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.	(b) (4)	03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 09:12:14
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:27:46
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	07 Oct 2020 19:54:07
User entered '96.4' F	Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Oral (Oral)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '48'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'bpm'	System	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '16'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'breaths/min'	System	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '117'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'mmHg'	System	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '80'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:20:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'mmHg'	System	07 Oct 2020 19:54:07

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:20:00

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered missing code ND - Not Done.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:20:00

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
	(b) (4)	
User entered missing code ND - Not Done.	Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User accepted default value 'Post-Dose (POSTDOSE)'	Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	(b) (4)	26 Jan 2021 20:01:09
User entered '16 Sep 2020'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	(b) (4)	26 Jan 2021 20:01:09
User entered '10:45'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '16 Sep 2020 10:45'	System	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '97.3' F	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Oral (Oral)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '51'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'bpm'	System	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '14'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'breaths/min'	System	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '125'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'mmHg'	System	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:47:53
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '78'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:20:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'mmHg'	System	07 Oct 2020 19:52:34

US3382284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:20:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:59:30
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:49:49

US3382284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:20:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 19:59:30
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:49:49

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:10
User signature succeeded.	(b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:10
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

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 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:10
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:10
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '16 Sep 2020'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:10
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '10:15'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '16 Sep 2020 10:15'	System	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:10
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Left Arm (LEFT ARM)'	(b) (4) Jayasree Krishnankutty (b) (4)	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:10
User entered 'ONCE'	System	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:20:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 15:41:55

US3382284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:20:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:37
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:50:05

US3382284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:20:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:37
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '16 Sep 2020'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:50:05

US3382284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:20:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:02:37
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Oct 2020 16:01:38
User entered '09:32' reason for change: Data Entry Error	Robin Dotson (b) (4)	09 Oct 2020 16:01:38
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 19:50:05
User entered empty.	Triny Cooper (b) (4)	07 Oct 2020 19:50:05

US3382284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '16 Sep 2020 09:32'	System	09 Oct 2020 16:01:38
User entered empty.	System	07 Oct 2020 19:50:05

US3382284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:20:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.	(b) (4)	03 Feb 2021 20:00:12
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	07 Oct 2020 19:50:57
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Oct 2020 19:50:57
User entered '16 Sep 2020' reason for change: Data Entry Error	Triny Cooper (b) (4)	07 Oct 2020 19:50:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	07 Oct 2020 19:50:47
User entered '16 2020' (non-conformant).	System	07 Oct 2020 19:50:47
	Triny Cooper (b) (4)	07 Oct 2020 19:50:47

US3382284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:20:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Triny Cooper (b) (4)	07 Oct 2020 19:50:47

US3382284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:20:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:00:12
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:50:47

US3382284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:20:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:00:12
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '09:40'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:50:47

US3382284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '16 Sep 2020 09:40'	System	07 Oct 2020 19:50:57
User entered '16 2020 09:40' (non-conformant).	System	07 Oct 2020 19:50:47

US3382284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:20:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Triny Cooper (b) (4)	07 Oct 2020 19:50:47

US3382284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:20:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:00:12
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:50:47

US3382284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:20:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:00:12
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:50:47

US3382284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered empty.	System	07 Oct 2020 19:50:47

US3382284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		03 Feb 2021 20:01:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Triny Cooper (b) (4)	07 Oct 2020 19:51:05

US3382284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:20:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '1'	System	07 Oct 2020 19:51:05

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:47:39', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '631e7bbc-b6ce-441b-b9c5-f056c95c62b9' User entered 'Yes (Y)'	System	16 Sep 2020 15:48:20
	System	16 Sep 2020 15:48:20

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:47:50', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '631e7bbc-b6ce-441b-b9c5-f056c95c62b9' User entered '97.3'	System	16 Sep 2020 15:48:20
	System	16 Sep 2020 15:48:20

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:47:56', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '631e7bbc-b6ce-441b-b9c5-f056c95c62b9' User entered 'No (N)'	System	16 Sep 2020 15:48:20
	System	16 Sep 2020 15:48:20

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:48:02', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '631e7bbc-b6ce-441b-b9c5-f056c95c62b9' User entered '16 Sep 2020 10:48'	System	16 Sep 2020 15:48:20
	System	16 Sep 2020 15:48:20

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '16 Sep 2020 10:35'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '16 Sep 2020 13:05'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:53:20', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '1c993a6e-2329-4de3-9c23-fc4c0f39ecb7' User entered 'Yes (Y)'	System	17 Sep 2020 16:54:30
	System	17 Sep 2020 16:54:30

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:54:21', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '1c993a6e-2329-4de3-9c23-fc4c0f39ecb7' User entered '97.1'	System	17 Sep 2020 16:54:30
	System	17 Sep 2020 16:54:30

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:54:24', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '1c993a6e-2329-4de3-9c23-fc4c0f39ecb7'	System	17 Sep 2020 16:54:30
User entered 'No (N)'	System	17 Sep 2020 16:54:30

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:54:27', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '1c993a6e-2329-4de3-9c23-fc4c0f39ecb7'	System	17 Sep 2020 16:54:30
User entered '17 Sep 2020 11:54'	System	17 Sep 2020 16:54:30

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '16 Sep 2020 14:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 2'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 3'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:20:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:30:06', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '75fb0299-c150-459c-a0a5-afff812a34ea' User entered 'Yes (Y)'	System	18 Sep 2020 18:30:22
	System	18 Sep 2020 18:30:22

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:20:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:30:10', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '75fb0299-c150-459c-a0a5-afff812a34ea' User entered '97.2'	System	18 Sep 2020 18:30:22
	System	18 Sep 2020 18:30:22

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:30:13', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '75fb0299-c150-459c-a0a5-afff812a34ea' User entered 'No (N)'	System	18 Sep 2020 18:30:22
	System	18 Sep 2020 18:30:22

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:30:17', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '75fb0299-c150-459c-a0a5-afff812a34ea' User entered '18 Sep 2020 13:30'	System	18 Sep 2020 18:30:22
	System	18 Sep 2020 18:30:22

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 4'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 5'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 6'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:20:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:33:33', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '82ac6d87-0589-4670-a4b4-62d052e8daff' User entered 'Yes (Y)'	System	21 Sep 2020 17:33:51
	System	21 Sep 2020 17:33:51

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:20:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:33:41', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '82ac6d87-0589-4670-a4b4-62d052e8daff' User entered '97.3'	System	21 Sep 2020 17:33:51
	System	21 Sep 2020 17:33:51

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:33:46', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '82ac6d87-0589-4670-a4b4-62d052e8daff' User entered 'No (N)'	System	21 Sep 2020 17:33:51
	System	21 Sep 2020 17:33:51

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:33:49', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '82ac6d87-0589-4670-a4b4-62d052e8daff' User entered '21 Sep 2020 12:33'	System	21 Sep 2020 17:33:51
	System	21 Sep 2020 17:33:51

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 7'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:20:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:35:31', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'fb53c28c-189b-4e38-a577-bdce2418a33e' User entered 'Yes (Y)'	System	23 Sep 2020 14:35:51
	System	23 Sep 2020 14:35:51

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:20:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:35:39', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'fb53c28c-189b-4e38-a577-bdce2418a33e' User entered '97.2'	System	23 Sep 2020 14:35:51
	System	23 Sep 2020 14:35:51

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:35:43', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'fb53c28c-189b-4e38-a577-bdce2418a33e' User entered 'No (N)'	System	23 Sep 2020 14:35:51
	System	23 Sep 2020 14:35:51

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:35:48', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'fb53c28c-189b-4e38-a577-bdce2418a33e' User entered '23 Sep 2020 09:35'	System	23 Sep 2020 14:35:51
	System	23 Sep 2020 14:35:51

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:48:13', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '05187add-6b88-4af3-9691-de2041c635d2' User entered 'None (1)'	System	16 Sep 2020 15:49:21
	System	16 Sep 2020 15:49:21

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:48:50', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '05187add-6b88-4af3-9691-de2041c635d2' User entered 'No (N)'	System	16 Sep 2020 15:49:21
	System	16 Sep 2020 15:49:21

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:48:54', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '05187add-6b88-4af3-9691-de2041c635d2' User entered 'No (N)'	System	16 Sep 2020 15:49:21
	System	16 Sep 2020 15:49:21

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:16', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '05187add-6b88-4af3-9691-de2041c635d2'	System	16 Sep 2020 15:49:21
User entered 'None (1)'	System	16 Sep 2020 15:49:21

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:18', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '05187add-6b88-4af3-9691-de2041c635d2' User entered '16 Sep 2020 10:49'	System	16 Sep 2020 15:49:21
	System	16 Sep 2020 15:49:21

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '16 Sep 2020 10:35'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '16 Sep 2020 13:05'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:54:36', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '5d58e5f9-cf27-4fc1-bd7d-8e8e9cd215aa' User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 16:55:09
	System	17 Sep 2020 16:55:09

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:54:58', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '5d58e5f9-cf27-4fc1-bd7d-8e8e9cd215aa' User entered 'No (N)'	System	17 Sep 2020 16:55:09
	System	17 Sep 2020 16:55:09

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:54:56', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '5d58e5f9-cf27-4fc1-bd7d-8e8e9cd215aa' User entered 'No (N)'	System	17 Sep 2020 16:55:09
	System	17 Sep 2020 16:55:09

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:03', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '5d58e5f9-cf27-4fc1-bd7d-8e8e9cd215aa' User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 16:55:09
	System	17 Sep 2020 16:55:09

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:05', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '5d58e5f9-cf27-4fc1-bd7d-8e8e9cd215aa' User entered '17 Sep 2020 11:55'	System	17 Sep 2020 16:55:09
	System	17 Sep 2020 16:55:09

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '16 Sep 2020 14:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 2'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 3'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:30:39', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ddb1e0f-0d85-4f7a-a713-a4424a2d58ff' User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 18:31:07
	System	18 Sep 2020 18:31:07

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:20:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:30:43', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ddb1e0f-0d85-4f7a-a713-a4424a2d58ff' User entered 'No (N)'	System	18 Sep 2020 18:31:07
	System	18 Sep 2020 18:31:07

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:30:59', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ddb1e0f-0d85-4f7a-a713-a4424a2d58ff' User entered 'No (N)'	System	18 Sep 2020 18:31:07
	System	18 Sep 2020 18:31:07

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:03', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ddb1e0f-0d85-4f7a-a713-a4424a2d58ff' User entered 'None (1)'	System	18 Sep 2020 18:31:07
	System	18 Sep 2020 18:31:07

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:06', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ddb1e0f-0d85-4f7a-a713-a4424a2d58ff' User entered '18 Sep 2020 13:31'	System	18 Sep 2020 18:31:07
	System	18 Sep 2020 18:31:07

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 4'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 5'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 6'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:33:57', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '50714bee-1348-4e0d-8a1f-a15d806c8571' User entered 'None (1)'	System	21 Sep 2020 17:34:15
	System	21 Sep 2020 17:34:15

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:20:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:01', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '50714bee-1348-4e0d-8a1f-a15d806c8571' User entered 'No (N)'	System	21 Sep 2020 17:34:15
	System	21 Sep 2020 17:34:15

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:04', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '50714bee-1348-4e0d-8a1f-a15d806c8571' User entered 'No (N)'	System	21 Sep 2020 17:34:15
	System	21 Sep 2020 17:34:15

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:08', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '50714bee-1348-4e0d-8a1f-a15d806c8571' User entered 'None (1)'	System	21 Sep 2020 17:34:15
	System	21 Sep 2020 17:34:15

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:11', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '50714bee-1348-4e0d-8a1f-a15d806c8571' User entered '21 Sep 2020 12:34'	System	21 Sep 2020 17:34:15
	System	21 Sep 2020 17:34:15

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 7'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:35:53', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'df26f82d-b38e-4643-807d-cdece8c5468f' User entered 'None (1)'	System	23 Sep 2020 14:36:11
	System	23 Sep 2020 14:36:11

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:20:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:35:56', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'df26f82d-b38e-4643-807d-cdece8c5468f' User entered 'No (N)'	System	23 Sep 2020 14:36:11
	System	23 Sep 2020 14:36:11

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:00', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'df26f82d-b38e-4643-807d-cdece8c5468f' User entered 'No (N)'	System	23 Sep 2020 14:36:11
	System	23 Sep 2020 14:36:11

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:20:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:04', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'df26f82d-b38e-4643-807d-cdece8c5468f' User entered 'None (1)'	System	23 Sep 2020 14:36:11
	System	23 Sep 2020 14:36:11

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:08', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'df26f82d-b38e-4643-807d-cdece8c5468f' User entered '23 Sep 2020 09:36'	System	23 Sep 2020 14:36:11
	System	23 Sep 2020 14:36:11

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:26', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '255a2d2f-7912-4c6f-964f-31a08dbca6f7' User entered 'None (0)'	System	16 Sep 2020 15:50:00
	System	16 Sep 2020 15:50:00

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:30', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '255a2d2f-7912-4c6f-964f-31a08dbca6f7' User entered 'None (0)'	System	16 Sep 2020 15:50:00
	System	16 Sep 2020 15:50:00

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:33', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '255a2d2f-7912-4c6f-964f-31a08dbca6f7' User entered 'None (0)'	System	16 Sep 2020 15:50:00
	System	16 Sep 2020 15:50:00

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:36', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '255a2d2f-7912-4c6f-964f-31a08dbca6f7' User entered 'None (0)'	System	16 Sep 2020 15:50:00
	System	16 Sep 2020 15:50:00

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:38', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '255a2d2f-7912-4c6f-964f-31a08dbca6f7' User entered 'None (0)'	System	16 Sep 2020 15:50:00
	System	16 Sep 2020 15:50:00

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:40', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '255a2d2f-7912-4c6f-964f-31a08dbca6f7' User entered 'None (0)'	System	16 Sep 2020 15:50:00
	System	16 Sep 2020 15:50:00

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:52', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '255a2d2f-7912-4c6f-964f-31a08dbca6f7' User entered 'No (N)'	System	16 Sep 2020 15:50:00
	System	16 Sep 2020 15:50:00

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-16T10:49:56', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '255a2d2f-7912-4c6f-964f-31a08dbca6f7' User entered '16 Sep 2020 10:49'	System	16 Sep 2020 15:50:00
	System	16 Sep 2020 15:50:00

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '16 Sep 2020 10:35'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '16 Sep 2020 13:05'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:10', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '0f734e3a-927f-4302-9815-66277a892fef' User entered 'None (0)'	System	17 Sep 2020 16:55:37
	System	17 Sep 2020 16:55:37

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:14', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '0f734e3a-927f-4302-9815-66277a892fef'	System	17 Sep 2020 16:55:37
User entered 'No interference with activity (1)'	System	17 Sep 2020 16:55:37

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:20', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '0f734e3a-927f-4302-9815-66277a892fef' User entered 'None (0)'	System	17 Sep 2020 16:55:37
	System	17 Sep 2020 16:55:37

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:23', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '0f734e3a-927f-4302-9815-66277a892fef' User entered 'None (0)'	System	17 Sep 2020 16:55:37
	System	17 Sep 2020 16:55:37

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:25', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '0f734e3a-927f-4302-9815-66277a892fef' User entered 'None (0)'	System	17 Sep 2020 16:55:37
	System	17 Sep 2020 16:55:37

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:28', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '0f734e3a-927f-4302-9815-66277a892fef' User entered 'None (0)'	System	17 Sep 2020 16:55:37
	System	17 Sep 2020 16:55:37

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:32', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '0f734e3a-927f-4302-9815-66277a892fef' User entered 'No (N)'	System	17 Sep 2020 16:55:37
	System	17 Sep 2020 16:55:37

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-17T11:55:34', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '0f734e3a-927f-4302-9815-66277a892fef' User entered '17 Sep 2020 11:55'	System	17 Sep 2020 16:55:37
	System	17 Sep 2020 16:55:37

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '16 Sep 2020 14:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 2'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 3'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:09', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '948f33c2-40c4-4da4-ad46-1731358cfa66' User entered 'None (0)'	System	18 Sep 2020 18:32:08
	System	18 Sep 2020 18:32:08

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:14', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '948f33c2-40c4-4da4-ad46-1731358cfa66'	System	18 Sep 2020 18:32:08
User entered 'No interference with activity (1)'	System	18 Sep 2020 18:32:08

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:17', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '948f33c2-40c4-4da4-ad46-1731358cfa66' User entered 'None (0)'	System	18 Sep 2020 18:32:08
	System	18 Sep 2020 18:32:08

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:23', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '948f33c2-40c4-4da4-ad46-1731358cfa66' User entered 'None (0)'	System	18 Sep 2020 18:32:08
	System	18 Sep 2020 18:32:08

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:25', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '948f33c2-40c4-4da4-ad46-1731358cfa66' User entered 'None (0)'	System	18 Sep 2020 18:32:08
	System	18 Sep 2020 18:32:08

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:32', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '948f33c2-40c4-4da4-ad46-1731358cfa66' User entered 'None (0)'	System	18 Sep 2020 18:32:08
	System	18 Sep 2020 18:32:08

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:35', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '948f33c2-40c4-4da4-ad46-1731358cfa66' User entered 'No (N)'	System	18 Sep 2020 18:32:08
	System	18 Sep 2020 18:32:08

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-18T13:31:40', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '948f33c2-40c4-4da4-ad46-1731358cfa66' User entered '18 Sep 2020 13:31'	System	18 Sep 2020 18:32:08
	System	18 Sep 2020 18:32:08

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 4'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 5'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 6'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:16', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ed2ee3c-3cea-4af0-8d86-9b19560c5e6d' User entered 'None (0)'	System	21 Sep 2020 17:34:53
	System	21 Sep 2020 17:34:53

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:24', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ed2ee3c-3cea-4af0-8d86-9b19560c5e6d' User entered 'None (0)'	System	21 Sep 2020 17:34:53
	System	21 Sep 2020 17:34:53

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:28', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ed2ee3c-3cea-4af0-8d86-9b19560c5e6d' User entered 'None (0)'	System	21 Sep 2020 17:34:53
	System	21 Sep 2020 17:34:53

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:32', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ed2ee3c-3cea-4af0-8d86-9b19560c5e6d' User entered 'None (0)'	System	21 Sep 2020 17:34:53
	System	21 Sep 2020 17:34:53

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:35', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ed2ee3c-3cea-4af0-8d86-9b19560c5e6d' User entered 'None (0)'	System	21 Sep 2020 17:34:53
	System	21 Sep 2020 17:34:53

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:42', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ed2ee3c-3cea-4af0-8d86-9b19560c5e6d' User entered 'None (0)'	System	21 Sep 2020 17:34:53
	System	21 Sep 2020 17:34:53

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:48', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ed2ee3c-3cea-4af0-8d86-9b19560c5e6d' User entered 'No (N)'	System	21 Sep 2020 17:34:53
	System	21 Sep 2020 17:34:53

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-21T12:34:51', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '9ed2ee3c-3cea-4af0-8d86-9b19560c5e6d' User entered '21 Sep 2020 12:34'	System	21 Sep 2020 17:34:53
	System	21 Sep 2020 17:34:53

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 7'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:13', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'dff304fa-bc08-4171-93af-50098c7dc228' User entered 'None (0)'	System	23 Sep 2020 14:36:57
	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:18', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'dff304fa-bc08-4171-93af-50098c7dc228'	System	23 Sep 2020 14:36:57
User entered 'No interference with activity (1)'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:32', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'dff304fa-bc08-4171-93af-50098c7dc228' User entered 'None (0)'	System	23 Sep 2020 14:36:57
	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:36', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'dff304fa-bc08-4171-93af-50098c7dc228' User entered 'None (0)'	System	23 Sep 2020 14:36:57
	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:40', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'dff304fa-bc08-4171-93af-50098c7dc228' User entered 'None (0)'	System	23 Sep 2020 14:36:57
	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:43', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'dff304fa-bc08-4171-93af-50098c7dc228' User entered 'None (0)'	System	23 Sep 2020 14:36:57
	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:51', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'dff304fa-bc08-4171-93af-50098c7dc228' User entered 'No (N)'	System	23 Sep 2020 14:36:57
	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-23T09:36:54', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'dff304fa-bc08-4171-93af-50098c7dc228' User entered '23 Sep 2020 09:36'	System	23 Sep 2020 14:36:57
	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	23 Sep 2020 14:36:57
User entered 'Day 8'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:20:00

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-24T11:45:11', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '34394900-038c-42b0-bd73-0bee6f7a1361'	System	24 Sep 2020 16:45:17
User entered 'No interference with activity (1)'	System	24 Sep 2020 16:45:17

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-24T11:45:13', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '34394900-038c-42b0-bd73-0bee6f7a1361' User entered '24 Sep 2020 11:45'	System	24 Sep 2020 16:45:17
	System	24 Sep 2020 16:45:17

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	23 Sep 2020 14:36:57
User entered 'Day 9'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:20:00

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-25T09:59:19', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'bcb679e9-4bf6-4ed9-9def-fa7307786936'	System	25 Sep 2020 14:59:26
User entered 'No interference with activity (1)'	System	25 Sep 2020 14:59:26

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-25T09:59:21', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'bcb679e9-4bf6-4ed9-9def-fa7307786936'	System	25 Sep 2020 14:59:26
User entered '25 Sep 2020 09:59'	System	25 Sep 2020 14:59:26

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	24 Sep 2020 16:45:17
User entered 'Day 10'	System	24 Sep 2020 16:45:17

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:20:00

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:45:17

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:45:17

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	25 Sep 2020 14:59:26
User entered 'Day 11'	System	25 Sep 2020 14:59:26

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:20:00

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-26T16:47:16', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '5678f9bd-9931-4ccc-b8e4-5e4e675ec07e' User entered 'None (0)'	System	26 Sep 2020 21:47:22
	System	26 Sep 2020 21:47:22

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:20:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-26T16:47:19', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '5678f9bd-9931-4ccc-b8e4-5e4e675ec07e' User entered '26 Sep 2020 16:47'	System	26 Sep 2020 21:47:22
	System	26 Sep 2020 21:47:22

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:59:26

US3382284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:59:26

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	23 Sep 2020 14:36:57
User entered 'Day 8'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-24T11:45:19', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'b6521775-8e16-47a2-b940-3da829387cf8' User entered 'No (N)'	System	24 Sep 2020 16:45:24
	System	24 Sep 2020 16:45:24

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-24T11:45:23', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'b6521775-8e16-47a2-b940-3da829387cf8' User entered '24 Sep 2020 11:45'	System	24 Sep 2020 16:45:24
	System	24 Sep 2020 16:45:24

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	23 Sep 2020 14:36:57
User entered 'Day 9'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-25T09:59:28', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'c3357dc6-8bed-4311-b0b3-db679b0475b6' User entered 'No (N)'	System	25 Sep 2020 14:59:35

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-25T09:59:31', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: 'c3357dc6-8bed-4311-b0b3-db679b0475b6' User entered '25 Sep 2020 09:59'	System	25 Sep 2020 14:59:35
	System	25 Sep 2020 14:59:35

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:36:57

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	24 Sep 2020 16:45:17
User entered 'Day 10'	System	24 Sep 2020 16:45:17

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:45:17

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:45:17

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
Data entry locked.	System	25 Sep 2020 14:59:26
User entered 'Day 11'	System	25 Sep 2020 14:59:26

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-26T16:47:23', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '06765dbb-ec26-4e0f-bcd2-1ac837f99793' User entered 'No (N)'	System	26 Sep 2020 21:47:29
	System	26 Sep 2020 21:47:29

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:20:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3C478754-08DD-4E60-BF8E-43A57129FA5B)', Time: '2020-09-26T16:47:25', User OID: 'PatientReportedOutcome (US3382284)', ODM File OID: '06765dbb-ec26-4e0f-bcd2-1ac837f99793' User entered '26 Sep 2020 16:47'	System	26 Sep 2020 21:47:29
	System	26 Sep 2020 21:47:29

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:20:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:59:26

US3382284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:20:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:44:50
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:59:26

US3382284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:24:51
User entered 'Yes (Y)'	Triny Cooper (b) (4)	07 Oct 2020 19:57:34

US3382284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:24:51
User entered '23 Sep 2020'	Triny Cooper (b) (4)	07 Oct 2020 19:57:34

US3382284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:24:51
User entered 'Contact Made (CONTACT MADE)'	Triny Cooper (b) (4)	07 Oct 2020 19:57:34

US3382284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:24:51
User entered empty.	Triny Cooper (b) (4)	07 Oct 2020 19:57:34

US3382284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:24:57
User entered 'Yes (Y)'	Triny Cooper (b) (4)	07 Oct 2020 19:57:39

US3382284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:20:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '1'	System	07 Oct 2020 19:57:39

US3382284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:26:03
User entered 'Yes (Y)'	Triny Cooper (b) (4)	07 Oct 2020 19:58:18

US3382284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Per CDM Re-query: Site response noted. According to Protocol, it is expected to perform the SC15 14 days at minimum (+3 days) after vaccination from V1D1. Exposure date is 16 Sep 2020 and SC15 date is 05 Oct 2020 which is greater than 17 days. Please reconcile and update as needed' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 08:08:38
Query 'Per CDM Re-query: Site response noted. According to Protocol, it is expected to perform the SC15 14 days at minimum (+3 days) after vaccination from V1D1. Exposure date is 16 Sep 2020 and SC15 date is 05 Oct 2020 which is greater than 17 days. Please reconcile and update as needed' answered with 'confirm date is correct as listed' (Site from DM).	Colleen Jacobsen (b) (4)	10 Nov 2020 22:42:53
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:26:03
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		09 Oct 2020 19:37:29
User opened query 'Per CDM Re-query: Site response noted. According to Protocol, it is expected to perform the SC15 14 days at minimum (+3 days) after vaccination from V1D1. Exposure date is 16 Sep 2020 and SC15 date is 05 Oct 2020 which is greater than 17 days. Please reconcile and update as needed' (Site from DM).		09 Oct 2020 19:37:01
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'updated' (Site from System).	Triny Cooper (b) (4)	07 Oct 2020 20:01:59

US3382284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Oct 2020 19:58:18
User entered '05 Oct 2020'	Triny Cooper (b) (4)	07 Oct 2020 19:58:18

US3382284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:26:03
User entered 'Contact Made (CONTACT MADE)'	Triny Cooper (b) (4)	07 Oct 2020 19:58:18

US3382284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:26:03
User entered empty.	Triny Cooper (b) (4)	07 Oct 2020 19:58:18

US3382284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:26:09
User entered 'Yes (Y)'	Triny Cooper (b) (4)	07 Oct 2020 20:00:12

US3382284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:20:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered '1'	System	07 Oct 2020 20:00:12

US3382284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:29:33
User entered 'Yes (Y)'	Triny Cooper (b) (4)	07 Oct 2020 20:01:07

US3382284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:29:33
User entered '07 Oct 2020'	Triny Cooper (b) (4)	07 Oct 2020 20:01:07

US3382284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:29:33
User entered 'Contact Made (CONTACT MADE)'	Triny Cooper (b) (4)	07 Oct 2020 20:01:07

US3382284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:20:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 16:29:33
User entered empty.	Triny Cooper (b) (4)	07 Oct 2020 20:01:07

US3382284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
DataPoint Verified.		07 Apr 2021 23:42:41
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
DataPoint Un-verified.	(b) (4) Colleen Jacobsen (b) (4)	26 Jan 2021 17:35:46
User entered 'No (N)' reason for change: Data Entry Error	Colleen Jacobsen (b) (4)	26 Jan 2021 17:35:46
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:29:37
User entered 'Yes (Y)'	Triny Cooper (b) (4)	07 Oct 2020 20:01:14

US3382284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:20:00

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:19:11
User entered empty.	System	26 Jan 2021 17:35:46
User entered '1'	System	07 Oct 2020 20:01:14

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02
Data entry locked.	System	16 Sep 2020 15:41:55
User entered 'Day 64'	System	16 Sep 2020 15:41:55

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[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)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Have you been exposed to someone with 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)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[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)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[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)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02
Data entry locked.	System	16 Sep 2020 15:41:55
User entered '16 Nov 2020 00:01'	System	16 Sep 2020 15:41:55

US3382284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:20:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 08:52:02
Data entry locked.	System	16 Sep 2020 15:41:55
User entered '20 Nov 2020 23:59'	System	16 Sep 2020 15:41:55

US3382284

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:20:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:51:23
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:28:30
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:56:14
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - 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)	09 Oct 2020 15:31:02
Data point term sent to Coder	(b) (4)	
User entered 'fatigue'	System	09 Oct 2020 15:29:53
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:56:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:56:31
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:56:35
User signature succeeded.	(b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 17:56:39
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 10:49:35
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'This is fatigue present a day after the 7-day post-dose 1 period and therefore is an AE. Subject had stated that fatigue is episodic' (Site from DM).	Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:26:50
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 16SEP2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:05:39
User entered '23 Sep 2020'	Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		10 Mar 2021 08:52:19
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 15:44:01
DataPoint Verified.		3 Feb 2021 17:56:43
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:56:46
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '25 Sep 2020'	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	10 Mar 2021 08:52:21
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:56:50
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:56:52
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:56:59
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:57:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 17:57:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:57:12
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:57:16
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 17:57:19
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:57:21
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:57:23
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:57:25
User signature succeeded.	(b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:57:27
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:57:44
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Related (RELATED)'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:57:57
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Not Related (NOT RELATED)'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:58:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'None (NONE)'	(b) (4)	
	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:58:12
User signature succeeded.	(b) (4)	26 Jan 2021 20:01:09
User entered '1'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:58:20
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
	(b) (4)	
User entered '0'	Michelle Jackson (b) (4)	09 Oct 2020 15:29:17
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:58:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 15:44:01
DataPoint Verified.		3 Feb 2021 17:58:28
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 17:58:29
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 17:58:32
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Michelle Jackson (b) (4) (b) (4)	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered '0'	System	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered '0'	System	09 Oct 2020 15:29:17

US3382284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:20:00

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:29:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:22
User entered 'USA-US096-2020-mRNA-1273-P301000003'	System	09 Nov 2020 19:26:18
User entered 'New'	(b) (4), (b) (6)	09 Nov 2020 19:26:18

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 17:59:30
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Gastric neoplasms malignant, PT: Gastric cancer, LLT: Gastric cancer - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 22:10:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:10:25
Data point term sent to Coder	System	06 Nov 2020 22:09:21
User entered 'Gastric cancer'	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:00:01
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:00:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:11:00
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:01:19
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '29 Oct 2020'	(b) (4)	
	Sikhongi Phungwayo	06 Nov 2020 22:08:56
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:36
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	03 Feb 2021 20:30:26
User entered empty; reason for change Data Entry Error	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:30:26
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	03 Feb 2021 20:07:22
Signature has been broken.	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:07:22
User entered '16:00' reason for change: Data Entry Error	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:07:22
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 20:01:09
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Nov 2020 22:22:44
User entered empty; reason for change Data Entry Error	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:22:44
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Nov 2020 22:08:56
User entered '16:00'	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	03 Feb 2021 20:30:26
User entered '29 Oct 2020 16:00'	System	03 Feb 2021 20:07:22
User entered empty.	System	06 Nov 2020 22:22:44
User entered '29 Oct 2020 16:00'	System	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:03:13
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:04:00
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:20:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'SUBJECT WITHDREW CONSENT, THEREBY THE END DATE WILL NOT BE KNOWN' (Site from Safety).	Sinikka Green (b) (4) (b) (4)	16 Dec 2020 19:36:46
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 21:32:44
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		09 Dec 2020 13:18:55
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Ongoing Chronic Diagnosis, no end date. Status unknown since subject is non-responsive' (Site from Safety).	Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:32:14
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:55:24
User entered empty.	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 20:36:41
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sikhongi Phungwayo	06 Nov 2020 22:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User closed query 'Per source, severity is moderate. Please reconcile, thank you.' (Site from CRA).	(b) (4)	22 Feb 2021 04:07:59
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:43
Query 'Per source, severity is moderate. Please reconcile, thank you.' answered with 'reviewed ' (Site from CRA).	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:07:36
Signature has been broken.	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:07:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:07:22
User opened query 'Per source, severity is moderate. Please reconcile, thank you.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 18:07:16
User signature succeeded.	Sinikka Green (b) (4) (b) (4)	26 Jan 2021 20:01:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:07:44
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:07:55
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 18:08:15
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'PV Query: Please consider deleting seriousness criterion "life-threatening", as described, the subject was not at imminent risk of death at the time of the event' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 13:19:03
User closed query 'PV Query: Please provide the rationale behind life-threatening serious criterion. Was the subject's life in immediate danger due to the event?' (Site from Safety).	(b) (4)	09 Dec 2020 13:19:00
Query 'PV Query: Please consider deleting seriousness criterion "life-threatening", as described, the subject was not at imminent risk of death at the time of the event' answered with 'Removed' (Site from Safety).	Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:33:32
Query 'PV Query: Please provide the rationale behind life-threatening serious criterion. Was the subject's life in immediate danger due to the event?' answered with 'Resolved ' (Site from Safety).	Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:33:24
User entered '0' reason for change: Data Entry Error	Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:31:11
User opened query 'PV Query: Please consider deleting seriousness criterion "life-threatening", as described, the subject was not at imminent risk of death at the time of the event' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:59:02
User opened query 'PV Query: Please provide the rationale behind life-threatening serious criterion. Was the subject's life in immediate danger due to the event?' (Site from Safety).	(b) (4)	16 Nov 2020 16:58:36
User entered '1'	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:08:24
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:00:24
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Subject not hospitalized' (Site from System).	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:38:48
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	06 Nov 2020 22:08:56
User entered '0'	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:08:54
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sikhongi Phungwayo	06 Nov 2020 22:08:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:08:59
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sikhongi Phungwayo	06 Nov 2020 22:08:56
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:09:01
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4)	
	Sikhongi Phungwayo	06 Nov 2020 22:08:56
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 15:44:01
DataPoint Verified.		3 Feb 2021 18:09:04
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sikhongi Phungwayo	06 Nov 2020 22:08:56
	(b) (4)	

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 15:44:01
DataPoint Verified.		3 Feb 2021 18:09:07
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:09:09
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:09:11
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '1'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:09:14
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Not Related (NOT RELATED)'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:09:21
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Not Related (NOT RELATED)'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

US3382284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:09:25
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Per CDM: "Action taken with investigational product" is answered as "Investigation product withdrawn", however "Dosing discontinuation" is not entered. Please consider entering dosing discontinuation form and if subject does not continued on follow-up period then please also enter data under end of study/Study discontinuation. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 07:33:40
Query 'Per CDM: "Action taken with investigational product" is answered as "Investigation product withdrawn", however "Dosing discontinuation" is not entered. Please consider entering dosing discontinuation form and if subject does not continued on follow-up period then please also enter data under end of study/Study discontinuation. Thank you!' answered with 'UPDATED' (Site from DM).	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:33:26
User opened query 'Per CDM: "Action taken with investigational product" is answered as "Investigation product withdrawn", however "Dosing discontinuation" is not entered. Please consider entering dosing discontinuation form and if subject does not continued on follow-up period then please also enter data under end of study/Study discontinuation. Thank you!' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:57:30
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 22:22:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 22:22:44
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:22:44
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 22:08:56
User entered empty.	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:09:40
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 18:09:45
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:33:47
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UNKNOWN MEDS, PT WITHDREW CONSENT BEFORE HE PROVIDED THIS INFO' (Site from DM).	Sinikka Green (b) (4)	13 Jan 2021 16:33:43
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 14:00:49
User entered '1'	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 18:09:56
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 07:33:50
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'PT WITHDREW CONSENT BEFORE HE COULD PROVIDE SPECIFICS' (Site from DM).	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:36:22
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 14:00:37
User entered '1'	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:10:17
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:20:23
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'SUBJECT WITHDREW CONSENT THIS WILL NOT BE KNOWN' (Site from Safety).	Sinikka Green (b) (4) (b) (4)	16 Dec 2020 19:37:31
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 21:33:53
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 13:19:08
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Not able to get a hold of subject so outcome unknown' (Site from Safety).	Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:42:07
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:58:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:10:31
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User closed query 'Per DM CLR: SAE Narrative = BLOOD TESTS ORDERED TO CHECK FOR H.PYLORI. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 06:08:44
	(b) (4), (b) (6)	03 Feb 2021 20:36:56
Query 'Per DM CLR: SAE Narrative = BLOOD TESTS ORDERED TO CHECK FOR H.PYLORI. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Recorded in source and eCRF updated ' (Site from DM). DataPoint Un-verified.	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:15:29
	(b) (4), (b) (6)	03 Feb 2021 18:17:57
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 18:17:52
User opened query 'Per DM CLR: SAE Narrative = BLOOD TESTS ORDERED TO CHECK FOR H.PYLORI. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	30 Jan 2021 23:54:37
	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 20:23:32
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 20:23:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 20:23:25
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results including blood test for H. pylori. Please include units and reference ranges if applicable.' (Site from Safety).		14 Jan 2021 20:23:21
User closed query 'Per DM CLR: Narrative indicates that subject had "ENDOSCOPY W/ BIOPSY, CT SCAN, SUCRALFATE, & OMEPRAZOLE. However, these are not recorded in Concomitant Procedure and Concomitant Medication eCRF respectively. Please review and record these in their appropriate eCRFs. Otherwise, clarify.' (Site from DM).		14 Jan 2021 08:27:11
Query 'Per DM CLR: Narrative indicates that subject had "ENDOSCOPY W/ BIOPSY, CT SCAN, SUCRALFATE, & OMEPRAZOLE. However, these are not recorded in Concomitant Procedure and Concomitant Medication eCRF respectively. Please review and record these in their appropriate eCRFs. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:59
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'CON MEDS WE KNOW ABOUT ARE IN SYSTEM' (Site from Safety).	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:36:40
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'NO PMH' (Site from Safety).	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:36:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'SUBJECT WITHDREW CONSENT BEFORE PROVIDING THIS' (Site from Safety).	Sinikka Green (b) (4)	13 Jan 2021 16:34:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results including blood test for H. pylori. Please include units and reference ranges if applicable.' answered with 'SUBJECT DID NOT PROVIDE FURTHER INFO' (Site from Safety).	Sinikka Green (b) (4)	13 Jan 2021 16:33:55
User opened query 'Per DM CLR: Narrative indicates that subject had "ENDOSCOPY W/ BIOPSY, CT SCAN, SUCRALFATE, & OMEPRAZOLE. However, these are not recorded in Concomitant Procedure and Concomitant Medication eCRF respectively. Please review and record these in their appropriate eCRFs. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 14:00:58
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 16:07:48
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'None. Subject's past medical history not indicative of any predisposing risk factors. ' (Site from Safety).	Sikhongi Phungwayo (b) (4)	09 Dec 2020 16:32:29
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:57:47
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		16 Nov 2020 16:57:19

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:56:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results including blood test for H. pylori. Please include units and reference ranges if applicable.' (Site from Safety).		16 Nov 2020 16:55:53
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		16 Nov 2020 16:55:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Narrative](#)

Audit	User	Time (GMT)
User entered '06-OCT-2020: LEFT EPIGASTRIC DULL, CONSTANT, 7/10 NON-RADIATING PAIN BEGINS. NO OTHER SYMPTOMS AT THIS TIME. 12-OCT-2020: PCP ON-SITE VISIT. SUBJECTS REPORTS BLOOD TESTS ORDERED TO CHECK FOR H.PYLORI. 13-OCT-2020: SUBJECT CALLED RECEIVES RESULTS. INFORMED IT'S A GASTRIC ULCER. 17-OCT-2020: SUBJECT VISITS ER AT UNIVERSITY HOSPITAL SAN ANTONIO DUE TO PAIN NOW RADIATING TO LEFT FLANK. SUBJECT REPORTS NEWLY NOTICED WEIGHT LOSS AT THIS TIME. DISCHARGED AND REFERRED TO GI FOR ENDOSCOPY W/ BIOPSY. 22-OCT-2020: ENDOSCOPY W/ BIOPSY PERFORMED 29-OCT-2020: GIVEN DIAGNOSIS OF STAGE 1 GASTRIC CANCER. APPOINTMENT MADE WITH ONCOLOGIST FOR 08-DEC-2020. 31-OCT-2020: SUBJECT RETURNS TO ER DUE TO NOW 10/10 PAIN WITH RADIATION TO LEFT FLANK. CT SCAN DONE. RESULT: STAGE 1-2 GASTRIC CANCER (SUBMUCOSAL/MUSCLE INVASION). SWITCHED FROM MEDICATION PRESCRIBED AT PREVIOUS ER VISIT (SUCRALFATE) TO OMEPRAZOLE. WAITING FOR SUBJECT TO CALL BACK FOR MEDICATION DOSAGE DETAILS AS HE WAS AT WORK AND COULDN'T TALK FOR LONG. TOLD TO SEE PCP FOR CARDIOLOGIST REFERRAL AS THERE'S AFFECTATION OF AN ARTERY WITH CLOSE PROXIMITY TO THE HEART. NOTE: SUBJECT ISN'T ABLE TO SEE PCP OR CARDIOLOGIST FOR FOLLOW-UP AS THEY DON'T HAVE INSURANCE. WORKING ON GETTING THAT SITUATED. Note: Diagnosis made 29-OCT-2020, but site notified today 06-NOV-2020.' reason for change: Data Entry Error	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:40:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Narrative](#)

Audit	User	Time (GMT)
User entered '06-OCT-2020: Left Epigastric dull, constant, 7/10 non-radiating pain begins. No other symptoms at this time. 12-OCT-2020: PCP on-site visit. Subjects reports blood tests ordered to check for H.Pylori. 13-OCT-2020: Subject called receives results. Informed it's a Gastric Ulcer. 17-OCT-2020: Subject visits ER at University Hospital San Antonio due to pain now radiating to left flank. Subject reports newly noticed weight loss at this time. Discharged and referred to GI for Endoscopy w/ Biopsy. 22-OCT-2020: Endoscopy w/ Biopsy performed 29-OCT-2020: Given diagnosis of Stage 1 Gastric Cancer. Appointment made with Oncologist for 08-DEC-2020. 31-OCT-2020: Subject returns to ER due to now 10/10 pain with radiation to left flank. CT scan done. Result: Stage 1-2 Gastric cancer (submucosal/muscle invasion). Switched from medication prescribed at previous ER visit (Sucralfate) to Omeprazole. Waiting for subject to call back for medication dosage details as he was at work and couldn't talk for long. Told to see PCP for Cardiologist referral as there's affectation of an artery with close proximity to the heart. Note: Subject isn't able to see PCP or Cardiologist for follow-up as they don't have insurance. Working on getting that situated.'	Sikhongi Phungwayo (b) (4)	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered '1'	System	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered '1'	System	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:20:00

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered '0'	System	06 Nov 2020 22:08:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Mar 2021 15:28:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 15:28:05
Data point term sent to Coder	System	05 Mar 2021 15:25:17
User entered 'Abdominal pain'	Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 15:44:01
DataPoint Verified.		1 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'Yes (Y)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'No (N)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'No (N)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 15:44:01
DataPoint Verified.		1 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '06 Oct 2020'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User closed query 'Per CDM: AE started more than 60 days ago, please clarify if end date is available or it is still ongoing. Thank you!' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 06:57:55
	(b) (4), (b) (6)	01 Apr 2021 15:14:33
Query 'Per CDM: AE started more than 60 days ago, please clarify if end date is available or it is still ongoing. Thank you!' ' answered with 'Please note that subject has withdrawn consent. AE of Abdominal pain is still ongoing as of the last contact with the patient. Status cannot be updated otherwise as the outcome is unknown.' (Site from DM).	Colleen Jacobsen (b) (4)	01 Apr 2021 15:01:00
User opened query 'Per CDM: AE started more than 60 days ago, please clarify if end date is available or it is still ongoing. Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:57:34
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'Yes (Y)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 15:44:01
DataPoint Verified.		1 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'No (N)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	(b) (4)	09 Mar 2021 17:12:42
User entered 'None (NONE)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '1'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '0'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:14:33
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered empty.	(b) (4) Jayasree Krishnankutty (b) (4)	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered '0'	System	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered '1'	System	05 Mar 2021 15:25:17

US3382284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:20:00

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:20:00

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:14
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sikhongi Phungwayo	08 Dec 2020 16:03:59
	(b) (4)	
User entered 'No (N)'	Triny Cooper (b) (4)	07 Oct 2020 20:02:46

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Dec 2020 14:18:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:18:44
Data point term sent to Coder	System	08 Dec 2020 16:06:49
User entered 'Morphine, Extended Release'	Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Gastric Cancer'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '15'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'mg (mg)'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 15:44:01
DataPoint Verified.		3 Feb 2021 18:46:05
User signature succeeded.	(b) (4)	26 Jan 2021 20:01:09
User entered 'other (OTHER)'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'q12h'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Oral (ORAL)'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sikhongi Phungwayo	08 Dec 2020 16:06:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '11 Nov 2020'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sikhongi Phungwayo	08 Dec 2020 16:06:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Sikhongi Phungwayo (b) (4)	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:20:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	08 Dec 2020 16:06:23

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Jan 2021 10:37:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 10:37:03
Data point term sent to Coder	System	13 Jan 2021 16:40:36
User entered 'SULCRAFATE'	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'ABDOMINAL PAIN/GASTRIC CANCER'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 16:42:26
User entered 'UNK' reason for change: Data Entry Error	System	13 Jan 2021 16:42:26
User entered 'UNK' reason for change: Data Entry Error	Sinikka Green (b) (4)	13 Jan 2021 16:42:26
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 16:39:42
User entered empty.	System	13 Jan 2021 16:39:42
User entered empty.	Sinikka Green (b) (4)	13 Jan 2021 16:39:42
User entered empty.	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Other (OTHER)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'UNKNOWN'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'unknown (UNKNOWN)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Oral (ORAL)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'UN Oct 2020'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:20:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	13 Jan 2021 16:39:42

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Jan 2021 09:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:51:48
Data point term sent to Coder	System	13 Jan 2021 16:43:39
User entered 'OMEPRAZOLE'	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'ABDOMINAL PAIN/GASTRIC CANCER'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'UNK'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Other (OTHER)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'UNK'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'unknown (UNKNOWN)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sinikka Green (b) (4)	13 Jan 2021 16:43:00
	(b) (4)	

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Oral (ORAL)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sinikka Green (b) (4)	13 Jan 2021 16:43:00
	(b) (4)	

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'UN Oct 2020'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '0'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:46:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'No (N)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:20:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User entered empty.	System	13 Jan 2021 16:43:00

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:20:00

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:43:13
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sinikka Green (b) (4)	13 Jan 2021 16:43:09
	(b) (4)	
User entered 'No (N)'	Triny Cooper (b) (4)	07 Oct 2020 20:02:54

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:20:00

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:43:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '29 Oct 2020'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:29

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:20:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:43:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'ENDOSCOPY WITH BIOPSIES'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:29

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:20:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:43:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Adverse Event (AE)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:29

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:20:00

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:43:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:29

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:20:00

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:43:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '31 Oct 2020'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:48

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:20:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:43:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'CT SCAN ABDOMEN'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:48

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:20:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:43:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'Adverse Event (AE)'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:43:48

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:20:00

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:43:05
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sinikka Green (b) (4)	13 Jan 2021 16:43:48
	(b) (4)	

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:20:00

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	01 Apr 2021 15:39:55
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered '12 Oct 2020' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	05 Mar 2021 16:09:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 10:59:06
User closed query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is prior the start date of AE #2 GASTRIC CANCER (29 OCT 2020-Ongoing). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 10:59:04
Query 'Data is required. Please complete.' answered with 'data not required.' (Site from System).	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:48:35
Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is prior the start date of AE #2 GASTRIC CANCER (29 OCT 2020-Ongoing). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'Wrong entry. This test was done as part of biopsy on 22 OCT-2020. Not a blood test. Entry removed.' (Site from DM).	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:48:12
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 20:46:45
DataPoint Un-verified.	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:46:45
Signature has been broken.	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:46:45
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:46:45
User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is prior the start date of AE #2 GASTRIC CANCER (29 OCT 2020-Ongoing). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:28:37
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:20:00

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:33:55
User entered '12 Oct 2020'	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:14:56

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:20:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	01 Apr 2021 15:39:55
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'Helicobacter pylori blood test' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	05 Mar 2021 16:09:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 10:59:07
Query 'Data is required. Please complete.' answered with 'data not required.' (Site from System).	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:48:37
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 20:46:45
DataPoint Un-verified.	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:46:45
Signature has been broken.	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:46:45
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:46:45
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:33:55
User entered 'Helicobacter Pylori Blood Test'	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:14:56

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:20:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.	(b) (4)	01 Apr 2021 15:39:55
User signature succeeded.	Sinikka Green (b) (4)	09 Mar 2021 17:12:42
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Jayasree Krishnankutty (b) (4)	05 Mar 2021 16:09:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 10:59:10
Query 'Data is required. Please complete.' answered with 'data not required.' (Site from System).	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:48:42
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 20:46:45
DataPoint Un-verified.	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:46:45
Signature has been broken.	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:46:45
User entered empty; reason for change Data Entry Error	Jayasree Krishnankutty (b) (4)	04 Mar 2021 20:46:45
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 20:33:55
User entered 'Adverse Event (AE)'	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:14:56

US3382284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:20:00

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:33:55
User entered empty.	Sikhongi Phungwayo (b) (4)	03 Feb 2021 20:14:56

US3382284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:20:00

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 00:39:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Per CDM: Please update date to appropriately reflect SAE. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 07:33:54
Query 'Per CDM: Please update date to appropriately reflect SAE. Thank you' answered with 'SUBJECT WITHDREW CONSENT THIS DAY' (Site from DM).	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:29:42
User entered '20 Nov 2020' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:29:38
User opened query 'Per CDM: Please update date to appropriately reflect SAE. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:25:10
User entered '8 Dec 2020'	Sikhongi Phungwayo (b) (4)	10 Dec 2020 14:34:23

US3382284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:20:00

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.	(b) (4)	08 Apr 2021 00:39:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE',However, no data is recorded on ' 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 07:34:02
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE',However, no data is recorded on ' 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'UPDATED' (Site from DM).	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:29:55
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE',However, no data is recorded on ' 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:02:25
User entered 'SAE (specify) (SAE)'	Sikhongi Phungwayo (b) (4)	10 Dec 2020 14:34:23

US3382284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:20:00

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.	(b) (4)	08 Apr 2021 00:39:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query "Per CDM: please record AE record number (i.e. AE #2, etc.) instead of details' .' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 07:32:52
Query "Per CDM: please record AE record number (i.e. AE #2, etc.) instead of details' .' answered with 'UPDATED' (Site from DM).	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:30:46
User entered 'AE #2' reason for change: Data Entry Error	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:30:41
User opened query "Per CDM: please record AE record number (i.e. AE #2, etc.) instead of details' .' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:01:15
User entered 'Subject does not want to continue due to Stage 3 Gastric Cancer diagnosis'	Sikhongi Phungwayo (b) (4)	10 Dec 2020 14:34:23

US3382284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:20:00

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.		07 Apr 2021 23:47:56
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '20 Nov 2020'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:31:51

US3382284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:20:00

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.	(b) (4)	07 Apr 2021 23:47:56
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	(b) (4)	18 Jan 2021 17:55:40
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	13 Jan 2021 16:31:51
User entered 'SAE (specify) (SAE)'	Sinikka Green (b) (4)	13 Jan 2021 16:31:51
	(b) (4)	

US3382284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:20:00

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.		07 Apr 2021 23:47:56
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered 'AE#2 (SAE) SUBJECT WITHDREW CONSENT'	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:31:51

US3382284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:20:00

If reason for discontinuation is [Death](#), main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.		07 Apr 2021 23:47:56
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty; reason for change Data Entry Error	(b) (4) Colleen Jacobsen (b) (4)	18 Jan 2021 17:55:40
User entered 'Adverse event (ADVERSE EVENT)'	Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:31:51

US3382284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:20:00

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.		07 Apr 2021 23:47:56
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:31:51

US3382284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:20:00

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.		07 Apr 2021 23:47:56
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4)	
	Sinikka Green (b) (4)	13 Jan 2021 16:31:51
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:20:00

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:33:21
DataPoint Verified.		07 Apr 2021 23:47:56
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered empty.	(b) (4) Sinikka Green (b) (4) (b) (4)	13 Jan 2021 16:31:51

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'USA-US096-2020-MRNA-1273-P301000003'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 13:19:22
Un-reviewed for Safety.	System	08 Dec 2020 16:31:11
User entered 'No (N)'	System	08 Dec 2020 16:31:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Sinikka'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Gregg'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Green'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Lucksinger'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6) '	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '1900 Cypress Creek Rd'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Cedar Park'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'TX'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '78613'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'US'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
Signature has been broken.	(b) (4)	04 Feb 2021 12:31:06
User entered '4'	System	04 Feb 2021 12:31:06
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '3'	(b) (4)	14 Jan 2021 20:26:02
User entered '2'	System	09 Dec 2020 13:19:33
User entered '1'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'USA-US096-2020-MRNA-1273-P301000003'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 13:19:22
Un-reviewed for Safety.	System	08 Dec 2020 16:31:11
User entered 'No (N)'	System	08 Dec 2020 16:31:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Sinikka'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Gregg'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Green'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Lucksinger'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6) '	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '1900 Cypress Creek Rd'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Cedar Park'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'TX'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '78613'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'US'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
Signature has been broken.	(b) (4)	04 Feb 2021 12:31:06
User entered '4'	System	04 Feb 2021 12:31:06
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '3'	(b) (4)	14 Jan 2021 20:26:02
User entered '2'	System	09 Dec 2020 13:19:33
User entered '1'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:20:00

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 20:39:15
DataPoint Un-verified.		03 Feb 2021 18:50:54
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '09/Nov/2020 19:26'	(b) (4) System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:20:00

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 20:39:15
DataPoint Un-verified.		03 Feb 2021 18:50:54
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '1'		09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'USA-US096-2020-MRNA-1273-P301000003'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 13:19:22
Un-reviewed for Safety.	System	08 Dec 2020 16:31:11
User entered 'No (N)'	System	08 Dec 2020 16:31:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Sinikka'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Gregg'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Green'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Lucksinger'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
	System	14 Jan 2021 20:26:02
User entered (b) (6) '	System	14 Jan 2021 20:26:02
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '1900 Cypress Creek Rd'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Cedar Park'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'TX'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '78613'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'US'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
Signature has been broken.	(b) (4)	04 Feb 2021 12:31:06
User entered '4'	System	04 Feb 2021 12:31:06
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '3'	(b) (4)	14 Jan 2021 20:26:02
User entered '2'	System	09 Dec 2020 13:19:33
User entered '1'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:20:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 20:39:15
DataPoint Un-verified.		03 Feb 2021 18:50:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '09/Dec/2020 13:19'	(b) (4) System	09 Dec 2020 13:19:33

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:20:00

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 20:39:15
DataPoint Un-verified.		03 Feb 2021 18:50:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 13:19:33

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'USA-US096-2020-MRNA-1273-P301000003'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 13:19:22
Un-reviewed for Safety.	System	08 Dec 2020 16:31:11
User entered 'No (N)'	System	08 Dec 2020 16:31:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Sinikka'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Gregg'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Green'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Lucksinger'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6) '	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '1900 Cypress Creek Rd'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered '(b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Cedar Park'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'TX'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '78613'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'US'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
Signature has been broken.	(b) (4)	04 Feb 2021 12:31:06
User entered '4'	System	04 Feb 2021 12:31:06
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '3'	(b) (4)	14 Jan 2021 20:26:02
User entered '2'	System	09 Dec 2020 13:19:33
User entered '1'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:20:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 20:39:15
DataPoint Un-verified.		03 Feb 2021 18:50:59
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '14/Jan/2021 15:26'	(b) (4) System	14 Jan 2021 20:26:02

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:20:00

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 20:39:15
DataPoint Un-verified.		03 Feb 2021 18:50:59
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:26:02

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'USA-US096-2020-MRNA-1273-P301000003'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 13:19:22
Un-reviewed for Safety.	System	08 Dec 2020 16:31:11
User entered 'No (N)'	System	08 Dec 2020 16:31:11
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'No (N)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Yes (Y)'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Sinikka'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Gregg'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered 'Green'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Lucksinger'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6) '	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '1900 Cypress Creek Rd'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'Cedar Park'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'TX'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
Reviewed for Safety.		04 Feb 2021 12:30:56
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)'	System	14 Jan 2021 20:26:02
Reviewed for Safety.	System	14 Jan 2021 20:26:02
	(b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered '78613'	System	09 Nov 2020 19:26:18

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		03 Feb 2021 18:50:22
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:26:59
User entered 'US'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:20:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
Signature has been broken.	(b) (4)	04 Feb 2021 12:31:06
User entered '4'	System	04 Feb 2021 12:31:06
User signature succeeded.	Sinikka Green (b) (4)	26 Jan 2021 20:01:09
User entered '3'	(b) (4)	14 Jan 2021 20:26:02
User entered '2'	System	09 Dec 2020 13:19:33
User entered '1'	System	09 Nov 2020 19:26:38

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:20:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:10:57
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
User entered '04/Feb/2021 07:31'	(b) (4) System	04 Feb 2021 12:31:06

US3382284

Folder: SAE USA-US096-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:20:00

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:44:01
DataPoint Verified.		01 Apr 2021 15:10:57
User signature succeeded.	Sinikka Green (b) (4)	04 Feb 2021 18:29:08
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 12:31:06