

US3032187 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:50:15

All time stamps listed in this document are displayed in GMT

US3032187

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

[Participant ID](#)

US3032187

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

US3032187

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3032187

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	49
Age Units	YEARS
Age (Derived)	49
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3032187

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3032187

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3032187

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Were any significant conditions reported?

Yes ☒
No ☐

US3032187

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Dec 2020 19:47:58

Generated On: 09 Jun 2021 14:50:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:54 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:54
Height (<i>xxx.x</i>)	176.5 cm
Weight (<i>xxx.x</i>)	101.6 kg
BMI (<i>xxx.x</i>)	32.61402 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032187

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

US3032187

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

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 True

Resides in Nursing Home or Assisted Living Facility False

US3032187

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Nov 2020 22:08:04

Generated On: 09 Jun 2021 14:50:15

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 103158

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 ☒

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Oct 2020 15:33:21

Generated On: 09 Jun 2021 14:50:15

Height	ND - Not Done
Weight	ND - Not Done

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Oct 2020 15:33:21

Generated On: 09 Jun 2021 14:50:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	13:54 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:54
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Oct 2020 15:33:21

Generated On: 09 Jun 2021 14:50:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	15:29 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:29
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3032187

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 14:58 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 14:58

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

US3032187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 AUG 2020

Collection time (00:00-23:59)

14:25 (24 HR)

Collection date and time (derived)

11 AUG 2020 14:25

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:15	11 AUG 2020 14:15
Nasopharyngeal Swab 2	No		

US3032187

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 15:31

PC Open Date & Time

11 AUG 2020 15:18

PC Close Date & Time

11 AUG 2020 17:48

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	11 AUG 2020 20:57
PC Open Date & Time	11 AUG 2020 18:43
PC Close Date & Time	12 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 20:06

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 22:04

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 20:30

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 00:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 05:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 09:51

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 15:32

PC Open Date & Time

11 AUG 2020 15:18

PC Close Date & Time

11 AUG 2020 17:48

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

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

11 AUG 2020 20:58

PC Open Date & Time

11 AUG 2020 18:43

PC Close Date & Time

12 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 20:08

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

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

13 AUG 2020 22:05

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 20:30

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 19:33

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

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

17 AUG 2020 05:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

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

18 AUG 2020 05:41

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

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 ☐

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 15:32
PC Open Date & Time	11 AUG 2020 15:18
PC Close Date & Time	11 AUG 2020 17:48

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

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 ☐

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 20:59
PC Open Date & Time	11 AUG 2020 18:43
PC Close Date & Time	12 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

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 ☒

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:09
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

44 of 3715

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 22:05
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

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

46 of 3715

EAB) (1725)

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:28
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

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)

48 of 3715

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:33
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

50 of 3715

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 05:02
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

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 ☒

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 05:42
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 AUG 2020 22:05

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 19 AUG 2020 13:47

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 AUG 2020 12:25

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 AUG 2020 15:00

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 23 AUG 2020 09:35

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 22:05
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 13:47
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 AUG 2020 12:26
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 AUG 2020 15:00
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 09:35
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3032187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:44
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 13:25
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3032187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 12:47 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 12:47

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

US3032187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 SEP 2020

Collection time (00:00-23:59)

12:18 (24 HR)

Collection date and time (derived)

8 SEP 2020 12:18

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:06	8 SEP 2020 12:06
Nasopharyngeal Swab 2	No		

US3032187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:28:40

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

08 SEP 2020 13:24

PC Open Date & Time

08 SEP 2020 13:07

PC Close Date & Time

08 SEP 2020 15:37

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 22:09

PC Open Date & Time

08 SEP 2020 16:32

PC Close Date & Time

09 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 21:35

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 07:42

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 07:57

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

12 SEP 2020 22:56

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 10:28

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 09:46

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

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

08 SEP 2020 13:25

PC Open Date & Time

08 SEP 2020 13:07

PC Close Date & Time

08 SEP 2020 15:37

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

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

08 SEP 2020 22:10

PC Open Date & Time

08 SEP 2020 16:32

PC Close Date & Time

09 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 21:36

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

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

11 SEP 2020 09:53

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 07:57

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 22:57

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

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

14 SEP 2020 10:29

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

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

15 SEP 2020 09:46

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

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 ☐

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 13:25
PC Open Date & Time	08 SEP 2020 13:07
PC Close Date & Time	08 SEP 2020 15:37

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

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 ☐

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 22:11
PC Open Date & Time	08 SEP 2020 16:32
PC Close Date & Time	09 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

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 ☒

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 21:36
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

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 ☒

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 09:54
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

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 ☒

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 07:58
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

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 ☒

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 22:57
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

106 of 3715

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

Yes ☐

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

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 ☒

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 09:47
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:50:15

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

16 SEP 2020 10:58

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:50:15

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

17 SEP 2020 09:29

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:50:15

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

18 SEP 2020 09:55

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 14:50:15

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

19 SEP 2020 10:49

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 12

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

20 SEP 2020 07:16

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 13

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

21 SEP 2020 09:37

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 14

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

22 SEP 2020 06:46

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 15

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

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 16

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 06:53

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 17

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

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 18

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

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 SEP 2020 10:58

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 17 SEP 2020 09:29

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 10

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

18 SEP 2020 09:56

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 11

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 SEP 2020 10:49

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 12

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 SEP 2020 07:16

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 13

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 SEP 2020 09:37

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 14

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 22 SEP 2020 06:47

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 15

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 16

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 SEP 2020 06:53

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 17

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 18

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

None ☐

ACHES ALL OVER BODY

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

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 SEP 2020 10:58

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 SEP 2020 09:29

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 SEP 2020 09:56

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 19 SEP 2020 10:49

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 SEP 2020 07:16

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 SEP 2020 09:37

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 SEP 2020 06:47

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 15

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

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 24 SEP 2020 06:54

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

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

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 10:58
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 09:29
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 09:56
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 10:49
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 07:17
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

21 SEP 2020 09:37

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 SEP 2020 06:47
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 06:54
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 17

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3032187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 01 Oct 2020 21:56:14

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 01 Oct 2020 21:56:14

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 15:33:21

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:33:21

Generated On: 09 Jun 2021 14:50:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:01 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 13:01
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 15:33:21

Generated On: 09 Jun 2021 14:50:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3032187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 15:33:21

Generated On: 09 Jun 2021 14:50:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	13:15 (24 HR)
Collection date and time (derived)	6 OCT 2020 13:15

US3032187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 15:33:21

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 12:31:40

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 OCT 2020 09:30:03
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 20:15:03

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 08:17:51

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 14:08:24

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 16:16:01

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 17:11:39

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 DEC 2020 12:12:16
Patient Cloud Open Date & Time	03 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
172 of 3715	

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 15:00:40

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 18:08:52

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 11:24:07

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 08:34:54

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 18:16:31

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 16:27:41

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 06:45:41
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 09:00:37
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 06:55:49

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 09:00:28

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 18:30:06

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 00:01:42

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 MAR 2021 09:21:03
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission	
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 13:05:10

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 243

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

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

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

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

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

Fever (Temperature \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 ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 06:38:12

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 18:00:15

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 12:00:19

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

Patient Cloud Open Date & Time	26 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	30 AUG 2021 23:59
---	-------------------

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 404

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 677

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 733

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

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

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

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

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	25 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	29 AUG 2022 23:59
---	-------------------

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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 ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	22 SEP 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	26 SEP 2022 23:59
---	-------------------

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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 ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3032187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:50:15

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		07 MAR 2021 18:30:18

US3032187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 24 Nov 2020 20:28:41

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 24 Nov 2020 20:28:41

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Jan 2021 19:28:44

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Jan 2021 19:28:44

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Jan 2021 19:28:44

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:03:01

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:03:01

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3032187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

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.

US3032187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	13:07 (24 HR)
Collection date and time (derived)	11 MAR 2021 13:07

US3032187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 18:07:08

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 18:07:08

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 14 Apr 2021 19:21:48

Generated On: 09 Jun 2021 14:50:15

Date of Contact	7 DEC 2020
Time of Contact	12:45
Date and Time of Contact (derived)	7 DEC 2020 12:45
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

371 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

372 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	36.4 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	96.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

379 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

384 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

395 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

396 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		399 of 3715
EAB) (1725)		

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		403 of 3715
EAB) (1725)		

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

404 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

407 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

412 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

419 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

420 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

423 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

427 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

428 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

431 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

432 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

435 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

436 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

439 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	04 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

443 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

444 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

448 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

452 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

455 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

456 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	09 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

459 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Dec 2020 20:09:41

Generated On: 09 Jun 2021 14:50:15

Date of Visit	10 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	10 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Feb 2021 19:40:34

Generated On: 09 Jun 2021 14:50:15

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 11 DEC 2020

End Date 11 DEC 2020

Oxygen Saturation 93 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

463 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Feb 2021 19:40:34

Generated On: 09 Jun 2021 14:50:15

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

464 of 3715

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Feb 2021 19:40:34

Generated On: 09 Jun 2021 14:50:15

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Dec 2020 20:09:42

Generated On: 09 Jun 2021 14:50:15

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 DEC 2020
Day 5	Yes	14 DEC 2020
Day 7	Yes	17 DEC 2020
Day 9	Yes	22 DEC 2020
Day 14	Yes	27 DEC 2020
Day 21	Yes	31 DEC 2020
Day 28	Yes	12 JAN 2021

US3032187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Dec 2020 20:09:42

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Dec 2020 20:09:42

Generated On: 09 Jun 2021 14:50:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 DEC 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	10 DEC 2020 14:40
Height (xxx.x)	176.5 cm
Weight (xxx.x)	98.0 kg
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032187

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Dec 2020 20:09:42

Generated On: 09 Jun 2021 14:50:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032187

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 07 Jan 2021 19:17:03

Generated On: 09 Jun 2021 14:50:15

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 DEC 2020

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 18 Jan 2021 19:28:44

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Jan 2021 19:28:44

Generated On: 09 Jun 2021 14:50:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 15:10
Height (xxx.x)	175.2 cm
Weight (xxx.x)	95.5 kg
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Jan 2021 19:28:44

Generated On: 09 Jun 2021 14:50:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 18 Jan 2021 19:28:44

Generated On: 09 Jun 2021 14:50:15

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 JAN 2021

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 30 Jan 2021 16:50:28

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	20 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

Date of updated informed consent (<i>dd MMM yyyy</i>)	20 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	20 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 30 Jan 2021 16:50:28

Generated On: 09 Jun 2021 14:50:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Jan 2021 16:50:28

Generated On: 09 Jun 2021 14:50:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 JAN 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 11:40
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Jan 2021 16:50:28

Generated On: 09 Jun 2021 14:50:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 JAN 2021
Time of assessment (00:00-23:59)	12:25 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 12:25
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Jan 2021 16:50:28

Generated On: 09 Jun 2021 14:50:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 30 Jan 2021 16:50:28

Generated On: 09 Jun 2021 14:50:15

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 20 JAN 2021

What was the treatment time? (00:00-23:59) 11:52 (24 HR)

Treatment Date and Time (derived) 20 JAN 2021 11:52

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

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Jan 2021 16:50:28

Generated On: 09 Jun 2021 14:50:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 JAN 2021

Collection time (00:00-23:59)

11:12 (24 HR)

Collection date and time (derived)

20 JAN 2021 11:12

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 19:55:43

Generated On: 09 Jun 2021 14:50:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00 - 23:59)	11:14
Collection Date and Time (derived)	20 JAN 2021 11:14

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 30 Jan 2021 16:50:28

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:25:16

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:25:16

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3032187

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:25:16

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:25:16

Generated On: 09 Jun 2021 14:50:15

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 08:05
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:25:16

Generated On: 09 Jun 2021 14:50:15

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	09:28 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 09:28
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3032187

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:25:16

Generated On: 09 Jun 2021 14:50:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032187

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:25:16

Generated On: 09 Jun 2021 14:50:15

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 FEB 2021

What was the treatment time? (00:00-23:59) 08:57 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 08:57

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

US3032187

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:25:16

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 04 Mar 2021 16:03:01

Generated On: 09 Jun 2021 14:50:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 04 Mar 2021 16:03:01

Generated On: 09 Jun 2021 14:50:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032187

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 APR 2021
Time of assessment (<i>00:00-23:59</i>)	13:16 (24 HR)
Vital Signs Date and Time (derived)	2 APR 2021 13:16
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032187

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

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.

US3032187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 APR 2021
Collection time (00:00-23:59)	13:16 (24 HR)
Collection date and time (derived)	2 APR 2021 13:16

US3032187

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Dec 2020 19:47:58

Generated On: 09 Jun 2021 14:50:15

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID	USA-US032-2020-MRNA-1273-P30 1000021
Adverse event	COVID 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	30 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	03 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	07 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

501 of 3715

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

SUBJECT CALLED TO REPORT
SAE. SUBJECT WAS STILL IN
HOSPITAL AT THE TIME OF THE
CALL. SUBJECT WILL CALL
AGAIN IN THE MORNING IF
DISCHARGED AND SIGN A
MEDICAL RELEASE FORM.
UPDATE 28 DEC: MEDICAL
RECORDS REVIEWED. IN
SUMMARY: SUBJECT
DIAGNOSED WITH COVID ON 30
NOV 2020. ON 03 DEC-04 DEC HE
BEGAN TO EXHIBIT SYMPTOMS
OF ENCEPHALOPATHY
INCLUDING LETHARGY AND
CONFUSION. HE WAS TAKEN
TO THE ER ON 03 DEC AND
ADMITTED. HE UTILIZED IV
DEXAMETHASONE AND
REMDESIVIR AND AT THIS
TIME DIAGNOSED WITH
DIABETES MELLITUS TYPE 2.
HIS HGBA1C WAS 12.5,
ADMITTING BLOOD GLUCOSE
466. HE WAS STARTED ON
BOTH LONG AND SHORT
ACTING INSULIN, LISINAPRIL,
AND SIMVASTATIN. ON
DISCHARGE HE CONTINUED
ORAL DEXAMETHASONE.
ADMISSION DATE 04 DEC,
DISCHARGE 07 DEC. HE WAS
ON OXYGEN VIA NASAL
CANNULA <24 HOURS.
UPDATE 10FEB: SUBJECT

Generated On: 09 Jun 2021 14:50:15

CALLED TO CLARIFY
 INFORMATION. STATES INITIAL
 COVID TEST PERFORMED AT
 PCP OFFICE ON 30NOV2020 DUE
 TO SYMPTOMS OF SHORTNESS
 OF BREATH, COUGH, BODY
 ACHES, MYALGIA,
 ARTHRALGIA, AND
 HEADACHE.

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

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID	USA-US032-2020-MRNA-1273-P30 1000021
Adverse event	DIABETES MELLITUS TYPE 2
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	3 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	07 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

505 of 3715

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

MEDICAL RECORDS
REVIEWED. IN SUMMARY:
SUBJECT DIAGNOSED WITH
COVID ON 30 NOV 2020. ON 03
DEC-04 DEC HE BEGAN TO
EXHIBIT SYMPTOMS OF
ENCEPHALOPATHY INCLUDING
LETHARGY AND CONFUSION.
HE WAS TAKEN TO THE ER ON
04 DEC AND ADMITTED. HE
UTILIZED IV DEXAMETHASONE
AND REMDESIVIR AND AT THIS
TIME DIAGNOSED WITH
DIABETES MELLITUS TYPE 2.
HIS HGBA1C WAS 12.5,
ADMITTING BLOOD GLUCOSE
466. HE WAS STARTED ON
BOTH LONG AND SHORT
ACTING INSULIN, LISINOPRIL,
AND SIMVASTATIN. ON
DISCHARGE HE CONTINUED
ORAL DEXAMETHASONE.
ADMISSION DATE 04 DEC,
DISCHARGE 07 DEC. HE WAS
ON OXYGEN VIA NASAL
CANNULA <24 HOURS.

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

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID

Adverse event

ACUTE SINUSITIS

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 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

508 of 3715

EAB) (1725)

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID

Adverse event

METABOLIC
ENCEPHALOPATHY

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)

3 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 DEC 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 ☐

PRODUCTION RELEASE (v12.003

510 of 3715

EAB) (1725)

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID

Adverse event

SORE THROAT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

512 of 3715

EAB) (1725)

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID

Adverse event

HYPERTENSION

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)

07 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

6 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

514 of 3715

EAB) (1725)

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID

Adverse event

HYPERLIPIDEMIA

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)

07 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

6 APR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

516 of 3715

EAB) (1725)

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID	
Adverse event	MYALGIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

518 of 3715

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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)	

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID

Adverse event

ARTHRALGIA

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)

11 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)

24 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

PRODUCTION RELEASE (v12.003

520 of 3715

EAB) (1725)

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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)	

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

AEID

Adverse event

ARTHRALGIA

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)

14 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 AUG 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

PRODUCTION RELEASE (v12.003

524 of 3715

EAB) (1725)

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 09 Apr 2021 18:07:07

Generated On: 09 Jun 2021 14:50:15

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 17:28:39

Generated On: 09 Jun 2021 14:50:15

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication LORATIDINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

527 of 3715

EAB) (1725)

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR SEASONAL
INFLUENZA

Dose per administration .5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

529 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

531 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

533 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication INSULIN ASPART

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 12

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

535 of 3715

EAB) (1725)

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication INSULIN DETEMIR

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 20

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

537 of 3715

EAB) (1725)

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

539 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

541 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 6

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

543 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 6 DEC 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

545 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 4 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify LITERS

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

547 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 100

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

549 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication AMOXICILLIN-CLAVULANATE

Prophylaxis Yes ☐
No ☒

Indication ACUTE SINUSITIS

Dose per administration 875/125

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

551 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		1 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SORE THROAT

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

553 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:37:33

Generated On: 09 Jun 2021 14:50:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
03 DEC 2020	BLOOD WORK	Adverse Event	
30 NOV 2020	COVID-19 PCR NASAL SWAB	Adverse Event	
03 DEC 2020	CT HEAD WITHOUT CONTRAST	Adverse Event	
03 DEC 2020	CHEST X-RAY	Adverse Event	

US3032187

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:50:15

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	08/DEC/2020 11:45
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	11/DEC/2020 09:59
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	29/DEC/2020 09:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (4)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	19/JAN/2021 13:14
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (5)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	22/JAN/2021 16:31
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (6)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	11/FEB/2021 09:41
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (7)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	12/FEB/2021 10:38
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (8)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	19/FEB/2021 11:38
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (9)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	22/FEB/2021 10:36
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (10)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	12/MAR/2021 07:09
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (11)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	15/MAR/2021 08:16
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

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (12)

Data signed: (b) (4) 18 Mar 2021 21:14:47

Generated On: 09 Jun 2021 14:50:15

SAEID	USA-US032-2020-MRNA-1273-P301000021
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	
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.	False

Audit

US3032187 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032187

Form: Participant Creation

Generated On: 09 Jun 2021 14:50:15

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:14:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'US3032187'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:04:24

US3032187

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:46:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:00:49

US3032187

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:46:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:04:25

US3032187

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[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 06:55:04
DataPoint Verified.		09 Mar 2021 17:46:16
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:00:49

US3032187

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'SCRN'	System	11 Aug 2020 20:00:49

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbecky (b) (4)	28 Sep 2020 17:28:40
User entered (b) (6) 1971'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:04:26

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '49'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'YEARS'	System	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered '49'	System	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Male (M)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:15

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:00
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:39:00

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '10 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'Aug 2020'	System	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered '2020'	System	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Amendment 2 (2)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:04:25

US3032187

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'I'	System	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:50:15

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:47:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3032187

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:50:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:48:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:53

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 20:48:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:48:15
Data point term sent to Coder	System	11 Aug 2020 20:47:03
User entered 'seasonal allergies'	Kelsey Kelley (b) (4)	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'Jan 2018'	System	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered '2018'	System	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered empty.	System	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:15

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered empty.	System	11 Aug 2020 20:46:09

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '13:54'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered '11 Aug 2020 13:54'	System	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '176.5' cm	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:41:55
DataPoint set to visible.	(b) (4) System	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '101.6' kg reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	01 Dec 2020 20:17:55
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	01 Dec 2020 20:17:46
User entered '107.6' kg reason for change: Data Entry Error	(b) (4)	
	Linden DeBoer (b) (4)	01 Dec 2020 20:17:46
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '101.6' kg	(b) (4)	
	Kelsey Kelley (b) (4)	11 Aug 2020 20:41:55
DataPoint set to visible.	(b) (4)	
	System	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered '32.61402'	System	01 Dec 2020 20:17:55
User entered '34.54004'	System	01 Dec 2020 20:17:46
Amendment Manager: User entered '32.61402'	System	16 Sep 2020 23:52:18
User entered '32.6'	System	11 Aug 2020 20:41:55
DataPoint set to visible.	System	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'kg/m2'	System	11 Aug 2020 20:41:55
DataPoint set to visible.	System	11 Aug 2020 20:02:02

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for "Not done" and not left empty). Please note that the unit should not remain. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 09:39:17
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for "Not done" and not left empty). Please note that the unit should not remain. Please update accordingly. ' answered with 'update' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:52:21
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:52:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:52:13
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for "Not done" and not left empty). Please note that the unit should not remain. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:20:08
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:28:40
User entered '36.9' C	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	06 Oct 2020 15:52:13
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	06 Oct 2020 15:52:13
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	11 Aug 2020 20:41:55
	(b) (4)	

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 09:39:18
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:52:24
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:52:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:52:13
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:20:15
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:28:40
User entered '89'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'bpm'	System	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 15:52:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 15:52:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:41:55
	(b) (4)	

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'breaths/min'	System	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	06 Oct 2020 15:52:13
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	06 Oct 2020 15:52:13
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
	(b) (4)	
User entered '122'	Kelsey Kelley (b) (4)	11 Aug 2020 20:41:55
	(b) (4)	

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'mmHg'	System	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:32
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	06 Oct 2020 15:52:13
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	06 Oct 2020 15:52:13
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
	(b) (4)	
User entered '79'	Kelsey Kelley (b) (4)	11 Aug 2020 20:41:55
	(b) (4)	

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User entered 'mmHg'	System	11 Aug 2020 20:41:55

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04

US3032187

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04

US3032187

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:38:21

US3032187

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:49:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 10:08:27
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 17:59:07
User entered '11 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:38:21

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

[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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

[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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

[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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'I'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

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 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:55:04
DataPoint Verified.		09 Mar 2021 17:50:32
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:40:24

US3032187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:38:03

US3032187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 Aug 2020'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:38:03
	(b) (4)	

US3032187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:38:03
	(b) (4)	

US3032187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'VISIT1'	System	11 Aug 2020 20:38:03

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:15

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:39:37

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:15

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:40:23
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:40:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 19:39:37
User entered '103158' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:39:37

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:39:37

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:15

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:01:46

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:15

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:01:46

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:15

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:01:46

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:15

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:01:46

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:01:46

US3032187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:15

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:52
User signature succeeded.	Keith Vrbicky (b) (4)	02 Nov 2020 22:08:04
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 07:35:44
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Update' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 19:10:44
User entered 'No (N)'	Kelsey Kelley (b) (4) (b) (4)	29 Oct 2020 19:10:37
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 10:45:41
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:35:48

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 10:33:28
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:29:40
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:29:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:29:35
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:39:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:28:40
User entered '176.5' cm	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:29:35
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:29:35
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
	(b) (4)	
User entered '101.6' kg	Kelsey Kelley (b) (4)	11 Aug 2020 20:43:45
	(b) (4)	

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.	(b) (4)	09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 10:33:28
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:29:40
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:29:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:29:35
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:39:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:28:40
User entered '176.5' cm	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:29:35
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:29:35
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
	(b) (4)	
User entered '101.6' kg	Kelsey Kelley (b) (4)	11 Aug 2020 20:43:45
	(b) (4)	

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '13:54'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered '11 Aug 2020 13:54'	System	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '89'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'bpm'	System	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'breaths/min'	System	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '122'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'mmHg'	System	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '79'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'mmHg'	System	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.	(b) (4)	09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 10:33:28
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'DATA UPDATED' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:29:40
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:29:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	07 Oct 2020 14:29:35
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:39:33
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 17:28:40
User entered '176.5' cm	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:43:45

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	07 Oct 2020 14:29:35
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	07 Oct 2020 14:29:35
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
	(b) (4)	
User entered '101.6' kg	Kelsey Kelley (b) (4)	11 Aug 2020 20:43:45
	(b) (4)	

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 09:05:40
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 min per protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:39
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 20:45:23
User entered '15:29'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered '11 Aug 2020 15:29'	System	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '64'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'bpm'	System	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'breaths/min'	System	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '140'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'mmHg'	System	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:50:57
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '81'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'mmHg'	System	11 Aug 2020 20:45:23

US3032187

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:51:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:21

US3032187

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:51:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:21

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:51:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:51:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:51:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:51:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:51:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '14:58'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered '11 Aug 2020 14:58'	System	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:51:52
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:51:52
User entered 'ONCE'	System	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 20:02:39

US3032187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:52:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:47:11

US3032187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:52:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:47:11

US3032187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:52:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '14:25'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:47:11

US3032187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered '11 Aug 2020 14:25'	System	11 Aug 2020 20:47:11

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:50:15

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:52:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:44

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:44

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:52:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:44

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:52:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '14:15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:44

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered '11 Aug 2020 14:15'	System	11 Aug 2020 20:46:44

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:44

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:52:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:44

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:52:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:44

US3032187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered empty.	System	11 Aug 2020 20:46:44

US3032187

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:52:50
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:46:53

US3032187

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'I'	System	11 Aug 2020 20:46:53

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:31:08', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd4f624db-e056-490a-84c7-68e1868ba0e0'	System	11 Aug 2020 20:31:25
User entered 'Yes (Y)'	System	11 Aug 2020 20:31:25

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:31:13', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd4f624db-e056-490a-84c7-68e1868ba0e0'	System	11 Aug 2020 20:31:25
User entered '98.3'	System	11 Aug 2020 20:31:25

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:31:18', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd4f624db-e056-490a-84c7-68e1868ba0e0'	System	11 Aug 2020 20:31:25
User entered 'No (N)'	System	11 Aug 2020 20:31:25

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:31:23', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd4f624db-e056-490a-84c7-68e1868ba0e0'	System	11 Aug 2020 20:31:25
User entered '11 Aug 2020 15:31'	System	11 Aug 2020 20:31:25

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Aug 2020 15:18'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Aug 2020 17:48'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 20:02:39

(

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:56:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bbb67b98-788a-4bde-b760-5879204d1241'	System	12 Aug 2020 01:57:19
User entered 'Yes (Y)'	System	12 Aug 2020 01:57:19

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:57:04', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bbb67b98-788a-4bde-b760-5879204d1241' User entered '98.0'	System	12 Aug 2020 01:57:19
	System	12 Aug 2020 01:57:19

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:57:09', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bbb67b98-788a-4bde-b760-5879204d1241'	System	12 Aug 2020 01:57:19
User entered 'No (N)'	System	12 Aug 2020 01:57:19

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:57:16', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bbb67b98-788a-4bde-b760-5879204d1241'	System	12 Aug 2020 01:57:19
User entered '11 Aug 2020 20:57'	System	12 Aug 2020 01:57:19

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Aug 2020 18:43'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 2'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:05:19', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a1d2c71e-edfb-413f-aaf3-06da7a6a10bf'	System	13 Aug 2020 01:06:35
User entered 'Yes (Y)'	System	13 Aug 2020 01:06:35

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:06:21', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a1d2c71e-edfb-413f-aaf3-06da7a6a10bf'	System	13 Aug 2020 01:06:35
User entered '97.8'	System	13 Aug 2020 01:06:35

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:06:27', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a1d2c71e-edfb-413f-aaf3-06da7a6a10bf'	System	13 Aug 2020 01:06:35
User entered 'No (N)'	System	13 Aug 2020 01:06:35

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:06:32', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a1d2c71e-edfb-413f-aaf3-06da7a6a10bf'	System	13 Aug 2020 01:06:35
User entered '12 Aug 2020 20:06'	System	13 Aug 2020 01:06:35

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 3'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:03:50', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '3647e1b3-23c4-43c9-9c96-588fc332814d'	System	14 Aug 2020 03:04:26
User entered 'Yes (Y)'	System	14 Aug 2020 03:04:26

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:04:05', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '3647e1b3-23c4-43c9-9c96-588fc332814d' User entered '96.4'	System	14 Aug 2020 03:04:26
	System	14 Aug 2020 03:04:26

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:04:15', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '3647e1b3-23c4-43c9-9c96-588fc332814d'	System	14 Aug 2020 03:04:26
User entered 'No (N)'	System	14 Aug 2020 03:04:26

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:04:24', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '3647e1b3-23c4-43c9-9c96-588fc332814d'	System	14 Aug 2020 03:04:26
User entered '13 Aug 2020 22:04'	System	14 Aug 2020 03:04:26

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 4'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:29:24', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b28d7ab8-054d-4643-a49c-ae078bb0eab0'	System	15 Aug 2020 01:30:13
User entered 'Yes (Y)'	System	15 Aug 2020 01:30:13

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:30:02', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b28d7ab8-054d-4643-a49c-ae078bb0eab0' User entered '97.2'	System	15 Aug 2020 01:30:13
	System	15 Aug 2020 01:30:13

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:30:08', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b28d7ab8-054d-4643-a49c-ae078bb0eab0'	System	15 Aug 2020 01:30:13
User entered 'No (N)'	System	15 Aug 2020 01:30:13

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:30:11', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b28d7ab8-054d-4643-a49c-ae078bb0eab0'	System	15 Aug 2020 01:30:13
User entered '14 Aug 2020 20:30'	System	15 Aug 2020 01:30:13

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 5'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-16T00:00:35', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f87902c2-4ddd-4c09-ac31-03e3b12cf8b4'	System	16 Aug 2020 05:00:54
User entered 'Yes (Y)'	System	16 Aug 2020 05:00:54

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-16T00:00:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f87902c2-4ddd-4c09-ac31-03e3b12cf8b4'	System	16 Aug 2020 05:00:54
User entered '97.5'	System	16 Aug 2020 05:00:54

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-16T00:00:47', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f87902c2-4ddd-4c09-ac31-03e3b12cf8b4'	System	16 Aug 2020 05:00:54
User entered 'No (N)'	System	16 Aug 2020 05:00:54

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-16T00:00:50', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f87902c2-4ddd-4c09-ac31-03e3b12cf8b4'	System	16 Aug 2020 05:00:54
User entered '16 Aug 2020 00:00'	System	16 Aug 2020 05:00:54

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 6'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '57ae7e88-4343-4a48-8fec-0de9c91cdcfc'	System	17 Aug 2020 10:01:20
User entered 'Yes (Y)'	System	17 Aug 2020 10:01:20

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:09', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '57ae7e88-4343-4a48-8fec-0de9c91cdcfc'	System	17 Aug 2020 10:01:20
User entered '97.0'	System	17 Aug 2020 10:01:20

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:13', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '57ae7e88-4343-4a48-8fec-0de9c91cdcfc'	System	17 Aug 2020 10:01:20
User entered 'No (N)'	System	17 Aug 2020 10:01:20

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:17', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '57ae7e88-4343-4a48-8fec-0de9c91cdcfc'	System	17 Aug 2020 10:01:20
User entered '17 Aug 2020 05:01'	System	17 Aug 2020 10:01:20

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 7'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T09:50:55', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6629436f-bd48-4fb9-acf8-bccd7a767741'	System	18 Aug 2020 14:51:11
User entered 'Yes (Y)'	System	18 Aug 2020 14:51:11

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T09:51:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6629436f-bd48-4fb9-acf8-bccd7a767741'	System	18 Aug 2020 14:51:11
User entered '97.8'	System	18 Aug 2020 14:51:11

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T09:51:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6629436f-bd48-4fb9-acf8-bccd7a767741'	System	18 Aug 2020 14:51:11
User entered 'No (N)'	System	18 Aug 2020 14:51:11

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T09:51:09', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6629436f-bd48-4fb9-acf8-bccd7a767741'	System	18 Aug 2020 14:51:11
User entered '18 Aug 2020 09:51'	System	18 Aug 2020 14:51:11

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:31:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f16e0b15-e79b-4b7a-952f-35344973286f'	System	11 Aug 2020 20:32:10
User entered 'None (1)'	System	11 Aug 2020 20:32:10

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:31:47', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f16e0b15-e79b-4b7a-952f-35344973286f'	System	11 Aug 2020 20:32:10
User entered 'No (N)'	System	11 Aug 2020 20:32:10

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:31:51', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f16e0b15-e79b-4b7a-952f-35344973286f'	System	11 Aug 2020 20:32:10
User entered 'No (N)'	System	11 Aug 2020 20:32:10

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f16e0b15-e79b-4b7a-952f-35344973286f'	System	11 Aug 2020 20:32:10
User entered 'None (1)'	System	11 Aug 2020 20:32:10

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:08', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f16e0b15-e79b-4b7a-952f-35344973286f'	System	11 Aug 2020 20:32:10
User entered '11 Aug 2020 15:32'	System	11 Aug 2020 20:32:10

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Aug 2020 15:18'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Aug 2020 17:48'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:57:32', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5e09abdf-bada-48c7-8b06-d9082eba7615'	System	12 Aug 2020 01:58:31
User entered 'None (1)'	System	12 Aug 2020 01:58:31

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:57:59', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5e09abdf-bada-48c7-8b06-d9082eba7615'	System	12 Aug 2020 01:58:31
User entered 'No (N)'	System	12 Aug 2020 01:58:31

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:58:10', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5e09abdf-bada-48c7-8b06-d9082eba7615'	System	12 Aug 2020 01:58:31
User entered 'No (N)'	System	12 Aug 2020 01:58:31

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:58:24', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5e09abdf-bada-48c7-8b06-d9082eba7615'	System	12 Aug 2020 01:58:31
User entered 'None (1)'	System	12 Aug 2020 01:58:31

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:58:29', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5e09abdf-bada-48c7-8b06-d9082eba7615'	System	12 Aug 2020 01:58:31
User entered '11 Aug 2020 20:58'	System	12 Aug 2020 01:58:31

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Aug 2020 18:43'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 2'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:07:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '2fa00892-2ac9-471b-9bbf-4f0f63e85a59'	System	13 Aug 2020 01:08:32
User entered 'None (1)'	System	13 Aug 2020 01:08:32

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:07:06', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '2fa00892-2ac9-471b-9bbf-4f0f63e85a59'	System	13 Aug 2020 01:08:32
User entered 'No (N)'	System	13 Aug 2020 01:08:32

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:07:10', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '2fa00892-2ac9-471b-9bbf-4f0f63e85a59'	System	13 Aug 2020 01:08:32
User entered 'No (N)'	System	13 Aug 2020 01:08:32

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:08:26', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '2fa00892-2ac9-471b-9bbf-4f0f63e85a59'	System	13 Aug 2020 01:08:32
User entered 'None (1)'	System	13 Aug 2020 01:08:32

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:08:29', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '2fa00892-2ac9-471b-9bbf-4f0f63e85a59'	System	13 Aug 2020 01:08:32
User entered '12 Aug 2020 20:08'	System	13 Aug 2020 01:08:32

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 3'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:04:39', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a13590ab-b430-48ee-9092-9e9e13a10ae6'	System	14 Aug 2020 03:05:11
User entered 'None (1)'	System	14 Aug 2020 03:05:11

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:04:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a13590ab-b430-48ee-9092-9e9e13a10ae6'	System	14 Aug 2020 03:05:11
User entered 'No (N)'	System	14 Aug 2020 03:05:11

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:04:52', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a13590ab-b430-48ee-9092-9e9e13a10ae6'	System	14 Aug 2020 03:05:11
User entered 'No (N)'	System	14 Aug 2020 03:05:11

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:04', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a13590ab-b430-48ee-9092-9e9e13a10ae6'	System	14 Aug 2020 03:05:11
User entered 'None (1)'	System	14 Aug 2020 03:05:11

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:08', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a13590ab-b430-48ee-9092-9e9e13a10ae6'	System	14 Aug 2020 03:05:11
User entered '13 Aug 2020 22:05'	System	14 Aug 2020 03:05:11

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 4'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:30:21', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7501171f-8c26-4df0-ae37-a44a7daafe99'	System	15 Aug 2020 01:30:58
User entered 'None (1)'	System	15 Aug 2020 01:30:58

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:30:25', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7501171f-8c26-4df0-ae37-a44a7daafe99'	System	15 Aug 2020 01:30:58
User entered 'No (N)'	System	15 Aug 2020 01:30:58

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:30:32', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7501171f-8c26-4df0-ae37-a44a7daafe99'	System	15 Aug 2020 01:30:58
User entered 'No (N)'	System	15 Aug 2020 01:30:58

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:30:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7501171f-8c26-4df0-ae37-a44a7daafe99'	System	15 Aug 2020 01:30:58
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 01:30:58

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:30:47', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7501171f-8c26-4df0-ae37-a44a7daafe99'	System	15 Aug 2020 01:30:58
User entered '14 Aug 2020 20:30'	System	15 Aug 2020 01:30:58

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 5'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:33:10', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '819fa30f-a143-41b6-a7d9-5ac686487a3b'	System	16 Aug 2020 00:33:37
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 00:33:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:33:12', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '819fa30f-a143-41b6-a7d9-5ac686487a3b'	System	16 Aug 2020 00:33:37
User entered 'No (N)'	System	16 Aug 2020 00:33:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:33:19', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '819fa30f-a143-41b6-a7d9-5ac686487a3b'	System	16 Aug 2020 00:33:37
User entered 'No (N)'	System	16 Aug 2020 00:33:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:33:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '819fa30f-a143-41b6-a7d9-5ac686487a3b'	System	16 Aug 2020 00:33:37
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 00:33:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:33:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '819fa30f-a143-41b6-a7d9-5ac686487a3b'	System	16 Aug 2020 00:33:37
User entered '15 Aug 2020 19:33'	System	16 Aug 2020 00:33:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 6'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:24', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a85d825b-0bf5-4b3e-8b2f-fe4e917c440e'	System	17 Aug 2020 10:01:40
User entered 'None (1)'	System	17 Aug 2020 10:01:40

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:27', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a85d825b-0bf5-4b3e-8b2f-fe4e917c440e'	System	17 Aug 2020 10:01:40
User entered 'No (N)'	System	17 Aug 2020 10:01:40

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:30', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a85d825b-0bf5-4b3e-8b2f-fe4e917c440e'	System	17 Aug 2020 10:01:40
User entered 'No (N)'	System	17 Aug 2020 10:01:40

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a85d825b-0bf5-4b3e-8b2f-fe4e917c440e'	System	17 Aug 2020 10:01:40
User entered 'None (1)'	System	17 Aug 2020 10:01:40

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a85d825b-0bf5-4b3e-8b2f-fe4e917c440e'	System	17 Aug 2020 10:01:40
User entered '17 Aug 2020 05:01'	System	17 Aug 2020 10:01:40

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 7'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:41:09', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bcd6819b-1633-4317-8bf0-6e0ccd464dde'	System	18 Aug 2020 10:41:37
User entered 'None (1)'	System	18 Aug 2020 10:41:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:41:12', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bcd6819b-1633-4317-8bf0-6e0ccd464dde'	System	18 Aug 2020 10:41:37
User entered 'No (N)'	System	18 Aug 2020 10:41:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:41:16', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bcd6819b-1633-4317-8bf0-6e0ccd464dde'	System	18 Aug 2020 10:41:37
User entered 'No (N)'	System	18 Aug 2020 10:41:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:41:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bcd6819b-1633-4317-8bf0-6e0ccd464dde'	System	18 Aug 2020 10:41:37
User entered 'None (1)'	System	18 Aug 2020 10:41:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:41:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bcd6819b-1633-4317-8bf0-6e0ccd464dde'	System	18 Aug 2020 10:41:37
User entered '18 Aug 2020 05:41'	System	18 Aug 2020 10:41:37

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:25', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b2a20c57-501a-4772-b717-ef7145473803'	System	11 Aug 2020 20:32:57
User entered 'None (0)'	System	11 Aug 2020 20:32:57

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b2a20c57-501a-4772-b717-ef7145473803'	System	11 Aug 2020 20:32:57
User entered 'None (0)'	System	11 Aug 2020 20:32:57

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b2a20c57-501a-4772-b717-ef7145473803'	System	11 Aug 2020 20:32:57
User entered 'None (0)'	System	11 Aug 2020 20:32:57

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b2a20c57-501a-4772-b717-ef7145473803'	System	11 Aug 2020 20:32:57
User entered 'None (0)'	System	11 Aug 2020 20:32:57

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b2a20c57-501a-4772-b717-ef7145473803'	System	11 Aug 2020 20:32:57
User entered 'None (0)'	System	11 Aug 2020 20:32:57

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b2a20c57-501a-4772-b717-ef7145473803'	System	11 Aug 2020 20:32:57
User entered 'None (0)'	System	11 Aug 2020 20:32:57

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:49', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b2a20c57-501a-4772-b717-ef7145473803'	System	11 Aug 2020 20:32:57
User entered 'No (N)'	System	11 Aug 2020 20:32:57

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T15:32:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b2a20c57-501a-4772-b717-ef7145473803'	System	11 Aug 2020 20:32:57
User entered '11 Aug 2020 15:32'	System	11 Aug 2020 20:32:57

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Aug 2020 15:18'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Aug 2020 17:48'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:58:36', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a691af24-3e11-4cec-90ab-d5b9cf8c3a0d'	System	12 Aug 2020 01:59:09
User entered 'None (0)'	System	12 Aug 2020 01:59:09

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:58:39', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a691af24-3e11-4cec-90ab-d5b9cf8c3a0d'	System	12 Aug 2020 01:59:09
User entered 'None (0)'	System	12 Aug 2020 01:59:09

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:58:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a691af24-3e11-4cec-90ab-d5b9cf8c3a0d'	System	12 Aug 2020 01:59:09
User entered 'None (0)'	System	12 Aug 2020 01:59:09

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:58:49', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a691af24-3e11-4cec-90ab-d5b9cf8c3a0d'	System	12 Aug 2020 01:59:09
User entered 'None (0)'	System	12 Aug 2020 01:59:09

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:58:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a691af24-3e11-4cec-90ab-d5b9cf8c3a0d'	System	12 Aug 2020 01:59:09
User entered 'None (0)'	System	12 Aug 2020 01:59:09

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:58:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a691af24-3e11-4cec-90ab-d5b9cf8c3a0d'	System	12 Aug 2020 01:59:09
User entered 'None (0)'	System	12 Aug 2020 01:59:09

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:59:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a691af24-3e11-4cec-90ab-d5b9cf8c3a0d'	System	12 Aug 2020 01:59:09
User entered 'No (N)'	System	12 Aug 2020 01:59:09

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-11T20:59:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a691af24-3e11-4cec-90ab-d5b9cf8c3a0d'	System	12 Aug 2020 01:59:09
User entered '11 Aug 2020 20:59'	System	12 Aug 2020 01:59:09

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Aug 2020 18:43'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 2'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:08:39', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '30666c53-38bd-4451-a44a-d801008d2f30'	System	13 Aug 2020 01:09:43
User entered 'No interference with activity (1)'	System	13 Aug 2020 01:09:43

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:09:02', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '30666c53-38bd-4451-a44a-d801008d2f30'	System	13 Aug 2020 01:09:43
User entered 'None (0)'	System	13 Aug 2020 01:09:43

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:09:16', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '30666c53-38bd-4451-a44a-d801008d2f30'	System	13 Aug 2020 01:09:43
User entered 'No interference with activity (1)'	System	13 Aug 2020 01:09:43

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:09:22', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '30666c53-38bd-4451-a44a-d801008d2f30'	System	13 Aug 2020 01:09:43
User entered 'None (0)'	System	13 Aug 2020 01:09:43

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:09:26', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '30666c53-38bd-4451-a44a-d801008d2f30'	System	13 Aug 2020 01:09:43
User entered 'None (0)'	System	13 Aug 2020 01:09:43

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:09:29', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '30666c53-38bd-4451-a44a-d801008d2f30'	System	13 Aug 2020 01:09:43
User entered 'None (0)'	System	13 Aug 2020 01:09:43

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:09:36', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '30666c53-38bd-4451-a44a-d801008d2f30'	System	13 Aug 2020 01:09:43
User entered 'No (N)'	System	13 Aug 2020 01:09:43

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-12T20:09:40', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '30666c53-38bd-4451-a44a-d801008d2f30'	System	13 Aug 2020 01:09:43
User entered '12 Aug 2020 20:09'	System	13 Aug 2020 01:09:43

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 3'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '96971f23-b172-40c9-8a3e-5227135ad817'	System	14 Aug 2020 03:05:49
User entered 'None (0)'	System	14 Aug 2020 03:05:49

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:19', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '96971f23-b172-40c9-8a3e-5227135ad817'	System	14 Aug 2020 03:05:49
User entered 'None (0)'	System	14 Aug 2020 03:05:49

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:23', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '96971f23-b172-40c9-8a3e-5227135ad817'	System	14 Aug 2020 03:05:49
User entered 'None (0)'	System	14 Aug 2020 03:05:49

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:26', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '96971f23-b172-40c9-8a3e-5227135ad817'	System	14 Aug 2020 03:05:49
User entered 'None (0)'	System	14 Aug 2020 03:05:49

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:30', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '96971f23-b172-40c9-8a3e-5227135ad817'	System	14 Aug 2020 03:05:49
User entered 'None (0)'	System	14 Aug 2020 03:05:49

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:35', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '96971f23-b172-40c9-8a3e-5227135ad817'	System	14 Aug 2020 03:05:49
User entered 'None (0)'	System	14 Aug 2020 03:05:49

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:42', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '96971f23-b172-40c9-8a3e-5227135ad817'	System	14 Aug 2020 03:05:49
User entered 'No (N)'	System	14 Aug 2020 03:05:49

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-13T22:05:46', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '96971f23-b172-40c9-8a3e-5227135ad817'	System	14 Aug 2020 03:05:49
User entered '13 Aug 2020 22:05'	System	14 Aug 2020 03:05:49

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 4'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:28:21', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '16654887-7b04-40dd-94a3-20121f434bb3'	System	15 Aug 2020 01:28:58
User entered 'None (0)'	System	15 Aug 2020 01:28:58

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:28:26', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '16654887-7b04-40dd-94a3-20121f434bb3'	System	15 Aug 2020 01:28:58
User entered 'No interference with activity (1)'	System	15 Aug 2020 01:28:58

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:28:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '16654887-7b04-40dd-94a3-20121f434bb3'	System	15 Aug 2020 01:28:58
User entered 'None (0)'	System	15 Aug 2020 01:28:58

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:28:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '16654887-7b04-40dd-94a3-20121f434bb3'	System	15 Aug 2020 01:28:58
User entered 'No interference with activity (1)'	System	15 Aug 2020 01:28:58

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:28:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '16654887-7b04-40dd-94a3-20121f434bb3'	System	15 Aug 2020 01:28:58
User entered 'None (0)'	System	15 Aug 2020 01:28:58

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:28:46', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '16654887-7b04-40dd-94a3-20121f434bb3'	System	15 Aug 2020 01:28:58
User entered 'None (0)'	System	15 Aug 2020 01:28:58

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:28:52', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '16654887-7b04-40dd-94a3-20121f434bb3'	System	15 Aug 2020 01:28:58
User entered 'No (N)'	System	15 Aug 2020 01:28:58

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-14T20:28:54', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '16654887-7b04-40dd-94a3-20121f434bb3'	System	15 Aug 2020 01:28:58
User entered '14 Aug 2020 20:28'	System	15 Aug 2020 01:28:58

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 5'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:32:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '04365f2d-ce56-4130-b5f7-e095d3021421' User entered 'None (0)'	System	16 Aug 2020 00:33:05
	System	16 Aug 2020 00:33:05

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:32:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '04365f2d-ce56-4130-b5f7-e095d3021421'	System	16 Aug 2020 00:33:05
User entered 'No interference with activity (1)'	System	16 Aug 2020 00:33:05

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:32:39', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '04365f2d-ce56-4130-b5f7-e095d3021421'	System	16 Aug 2020 00:33:05
User entered 'None (0)'	System	16 Aug 2020 00:33:05

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:32:43', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '04365f2d-ce56-4130-b5f7-e095d3021421'	System	16 Aug 2020 00:33:05
User entered 'No interference with activity (1)'	System	16 Aug 2020 00:33:05

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:32:47', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '04365f2d-ce56-4130-b5f7-e095d3021421'	System	16 Aug 2020 00:33:05
User entered 'None (0)'	System	16 Aug 2020 00:33:05

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:32:50', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '04365f2d-ce56-4130-b5f7-e095d3021421'	System	16 Aug 2020 00:33:05
User entered 'None (0)'	System	16 Aug 2020 00:33:05

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:32:57', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '04365f2d-ce56-4130-b5f7-e095d3021421'	System	16 Aug 2020 00:33:05
User entered 'No (N)'	System	16 Aug 2020 00:33:05

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-15T19:33:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '04365f2d-ce56-4130-b5f7-e095d3021421'	System	16 Aug 2020 00:33:05
User entered '15 Aug 2020 19:33'	System	16 Aug 2020 00:33:05

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 6'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:42', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '88b0c6d5-0885-4af0-9ccf-8732b9f1bbca'	System	17 Aug 2020 10:02:11
User entered 'None (0)'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '88b0c6d5-0885-4af0-9ccf-8732b9f1bbca'	System	17 Aug 2020 10:02:11
User entered 'None (0)'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:48', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '88b0c6d5-0885-4af0-9ccf-8732b9f1bbca'	System	17 Aug 2020 10:02:11
User entered 'None (0)'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:50', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '88b0c6d5-0885-4af0-9ccf-8732b9f1bbca'	System	17 Aug 2020 10:02:11
User entered 'No interference with activity (1)'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '88b0c6d5-0885-4af0-9ccf-8732b9f1bbca'	System	17 Aug 2020 10:02:11
User entered 'None (0)'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:01:55', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '88b0c6d5-0885-4af0-9ccf-8732b9f1bbca'	System	17 Aug 2020 10:02:11
User entered 'None (0)'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:02:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '88b0c6d5-0885-4af0-9ccf-8732b9f1bbca'	System	17 Aug 2020 10:02:11
User entered 'No (N)'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-17T05:02:06', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '88b0c6d5-0885-4af0-9ccf-8732b9f1bbca'	System	17 Aug 2020 10:02:11
User entered '17 Aug 2020 05:02'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 7'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:41:40', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6b736a66-4dbb-473a-9d36-31f3cd1fbaec'	System	18 Aug 2020 10:42:19
User entered 'None (0)'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:41:50', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6b736a66-4dbb-473a-9d36-31f3cd1fbaec'	System	18 Aug 2020 10:42:19
User entered 'None (0)'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:41:54', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6b736a66-4dbb-473a-9d36-31f3cd1fbaec'	System	18 Aug 2020 10:42:19
User entered 'None (0)'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:41:57', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6b736a66-4dbb-473a-9d36-31f3cd1fbaec'	System	18 Aug 2020 10:42:19
User entered 'No interference with activity (1)'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:42:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6b736a66-4dbb-473a-9d36-31f3cd1fbaec'	System	18 Aug 2020 10:42:19
User entered 'None (0)'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:42:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6b736a66-4dbb-473a-9d36-31f3cd1fbaec'	System	18 Aug 2020 10:42:19
User entered 'None (0)'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:42:10', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6b736a66-4dbb-473a-9d36-31f3cd1fbaec'	System	18 Aug 2020 10:42:19
User entered 'No (N)'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T05:42:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6b736a66-4dbb-473a-9d36-31f3cd1fbaec'	System	18 Aug 2020 10:42:19
User entered '18 Aug 2020 05:42'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	17 Aug 2020 10:02:11
User entered 'Day 8'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T22:05:36', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '797a3966-192e-4231-a95b-a75b2fcb9653'	System	19 Aug 2020 03:05:46
User entered 'No interference with activity (1)'	System	19 Aug 2020 03:05:46

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T22:05:40', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '797a3966-192e-4231-a95b-a75b2fcb9653'	System	19 Aug 2020 03:05:46
User entered '18 Aug 2020 22:05'	System	19 Aug 2020 03:05:46

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	18 Aug 2020 10:42:19
User entered 'Day 9'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-19T13:47:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4c50c530-9a5c-48f4-a888-021b2bc0581d'	System	19 Aug 2020 19:47:35
User entered 'No interference with activity (1)'	System	19 Aug 2020 19:47:35

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-19T13:47:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4c50c530-9a5c-48f4-a888-021b2bc0581d'	System	19 Aug 2020 19:47:35
User entered '19 Aug 2020 13:47'	System	19 Aug 2020 19:47:35

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	19 Aug 2020 03:05:46
User entered 'Day 10'	System	19 Aug 2020 03:05:46

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-20T12:25:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '11f5ac54-4236-412f-8c91-e364129740e6'	System	20 Aug 2020 18:26:02
User entered 'No interference with activity (1)'	System	20 Aug 2020 18:26:02

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-20T12:25:59', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '11f5ac54-4236-412f-8c91-e364129740e6'	System	20 Aug 2020 18:26:02
User entered '20 Aug 2020 12:25'	System	20 Aug 2020 18:26:02

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 03:05:46

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 03:05:46

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	19 Aug 2020 19:47:35
User entered 'Day 11'	System	19 Aug 2020 19:47:35

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-21T15:00:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4e8784f1-0db7-4582-b7fa-760a7d7140b9'	System	21 Aug 2020 20:00:38
User entered 'No interference with activity (1)'	System	21 Aug 2020 20:00:38

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-21T15:00:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4e8784f1-0db7-4582-b7fa-760a7d7140b9'	System	21 Aug 2020 20:00:38
User entered '21 Aug 2020 15:00'	System	21 Aug 2020 20:00:38

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 19:47:35

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 19:47:35

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	20 Aug 2020 18:26:02
User entered 'Day 12'	System	20 Aug 2020 18:26:02

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-23T09:35:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '767fb3ba-2eaf-4908-80f9-fa6e02d19660'	System	23 Aug 2020 14:35:35
User entered 'None (0)'	System	23 Aug 2020 14:35:35

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-23T09:35:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '767fb3ba-2eaf-4908-80f9-fa6e02d19660'	System	23 Aug 2020 14:35:35
User entered '23 Aug 2020 09:35'	System	23 Aug 2020 14:35:35

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 18:26:02

US3032187

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 18:26:02

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	17 Aug 2020 10:02:11
User entered 'Day 8'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T22:05:49', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '512b7d6c-ccb8-45a0-8b5e-df80a2c66167'	System	19 Aug 2020 03:05:58
User entered 'No (N)'	System	19 Aug 2020 03:05:58

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-18T22:05:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '512b7d6c-ccb8-45a0-8b5e-df80a2c66167'	System	19 Aug 2020 03:05:58
User entered '18 Aug 2020 22:05'	System	19 Aug 2020 03:05:58

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 10:02:11

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	18 Aug 2020 10:42:19
User entered 'Day 9'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-19T13:47:38', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '597d88e5-356d-4d4c-85ab-18f60a71f13f' User entered 'No (N)'	System	19 Aug 2020 19:47:46
	System	19 Aug 2020 19:47:46

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-19T13:47:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '597d88e5-356d-4d4c-85ab-18f60a71f13f' User entered '19 Aug 2020 13:47'	System	19 Aug 2020 19:47:46
	System	19 Aug 2020 19:47:46

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 10:42:19

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	19 Aug 2020 03:05:46
User entered 'Day 10'	System	19 Aug 2020 03:05:46

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-20T12:26:05', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '530fb883-63ee-4845-87c8-74df9f5a98e4'	System	20 Aug 2020 18:26:16
User entered 'No (N)'	System	20 Aug 2020 18:26:16

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-20T12:26:11', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '530fb883-63ee-4845-87c8-74df9f5a98e4'	System	20 Aug 2020 18:26:16
User entered '20 Aug 2020 12:26'	System	20 Aug 2020 18:26:16

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 03:05:46

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 03:05:46

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	19 Aug 2020 19:47:35
User entered 'Day 11'	System	19 Aug 2020 19:47:35

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-21T15:00:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c57ddc22-6b9f-4f77-b636-af3e8142cb71'	System	21 Aug 2020 20:00:44
User entered 'No (N)'	System	21 Aug 2020 20:00:44

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-21T15:00:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c57ddc22-6b9f-4f77-b636-af3e8142cb71'	System	21 Aug 2020 20:00:44
User entered '21 Aug 2020 15:00'	System	21 Aug 2020 20:00:44

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 19:47:35

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 19:47:35

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	20 Aug 2020 18:26:02
User entered 'Day 12'	System	20 Aug 2020 18:26:02

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-23T09:35:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a36c78d3-42d2-495e-98be-55b8ad8af834'	System	23 Aug 2020 14:35:44
User entered 'No (N)'	System	23 Aug 2020 14:35:44

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-08-23T09:35:40', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a36c78d3-42d2-495e-98be-55b8ad8af834'	System	23 Aug 2020 14:35:44
User entered '23 Aug 2020 09:35'	System	23 Aug 2020 14:35:44

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 18:26:02

US3032187

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 18:26:02

US3032187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	20 Aug 2020 02:16:42
	(b) (4)	

US3032187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '19 Aug 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:16:42

US3032187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:16:42

US3032187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:28
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:16:42

US3032187

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:34
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:16:46

US3032187

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'I'	System	20 Aug 2020 02:16:46

US3032187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:58:19

US3032187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '27 Aug 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:58:19

US3032187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:58:19

US3032187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:49
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:58:19

US3032187

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:54:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:58:23

US3032187

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'I'	System	08 Sep 2020 17:58:23

US3032187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:55:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Sep 2020 17:58:45
	(b) (4)	

US3032187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:55:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '01 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:58:45

US3032187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:55:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:58:45

US3032187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:55:20
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:58:45

US3032187

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 17:55:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:58:49

US3032187

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'I'	System	08 Sep 2020 17:58:49

US3032187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:55:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	08 Sep 2020 17:59:07
	(b) (4)	

US3032187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:55:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '08 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:59:07

US3032187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:55:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Clinic (Clinic)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:59:07

US3032187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'VISIT2'	System	08 Sep 2020 17:59:07

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User accepted default value 'Pre-Dose (PREDOSE)'	Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '8 Sep 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '11:44'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered '8 Sep 2020 11:44'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '37.0' C	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Oral (Oral)'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	08 Sep 2020 19:12:29
	(b) (4)	

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '64'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'bpm'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '16'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'breaths/min'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '130'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'mmHg'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '82'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'mmHg'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User accepted default value 'Post-Dose (POSTDOSE)'	Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '8 Sep 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '13:25'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered '8 Sep 2020 13:25'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '36.7' C	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Oral (Oral)'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '72'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'bpm'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '16'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'breaths/min'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '135'	(b) (4)	
	Russell Herstein (b) (4)	08 Sep 2020 19:12:29
	(b) (4)	

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'mmHg'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:19
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '80'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'mmHg'	System	08 Sep 2020 19:12:29

US3032187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:41

US3032187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '8 Sep 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:12:41

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:59:40

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	08 Sep 2020 17:59:40
	(b) (4)	

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:59:40

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 17:59:40

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '08 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:59:40

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '12:47'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:59:40

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered '08 Sep 2020 12:47'	System	08 Sep 2020 17:59:40

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 17:59:40

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:58:55
User entered 'ONCE'	System	08 Sep 2020 17:59:40

US3032187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 17:59:40

US3032187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:59:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:13:02

US3032187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:59:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '8 Sep 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:13:02

US3032187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:59:33
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '12:18'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:13:02

US3032187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered '8 Sep 2020 12:18'	System	08 Sep 2020 19:13:02

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:50:15

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:59:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '8 Sep 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:13:28

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:13:28

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:59:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4)	
	Russell Herstein (b) (4)	08 Sep 2020 19:13:28
	(b) (4)	

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:15

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:59:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '12:06'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:13:28

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered '8 Sep 2020 12:06'	System	08 Sep 2020 19:13:28

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Russell Herstein (b) (4)	08 Sep 2020 19:13:28

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:59:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:13:28

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:59:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	08 Sep 2020 19:13:28
	(b) (4)	

US3032187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered empty.	System	08 Sep 2020 19:13:28

US3032187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
DataPoint Verified.		09 Mar 2021 17:59:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	08 Sep 2020 19:13:34

US3032187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'I'	System	08 Sep 2020 19:13:34

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:23:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd3128253-2381-4cde-97fb-ef72ee8bad72'	System	08 Sep 2020 18:24:12
User entered 'Yes (Y)'	System	08 Sep 2020 18:24:12

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:23:58', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd3128253-2381-4cde-97fb-ef72ee8bad72'	System	08 Sep 2020 18:24:12
User entered '98.1'	System	08 Sep 2020 18:24:12

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:24:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd3128253-2381-4cde-97fb-ef72ee8bad72'	System	08 Sep 2020 18:24:12
User entered 'No (N)'	System	08 Sep 2020 18:24:12

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:24:09', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd3128253-2381-4cde-97fb-ef72ee8bad72'	System	08 Sep 2020 18:24:12
User entered '08 Sep 2020 13:24'	System	08 Sep 2020 18:24:12

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '08 Sep 2020 13:07'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '08 Sep 2020 15:37'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:08:10', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'e88cd0d7-545f-4a4a-85b0-2c2825dd9528'	System	09 Sep 2020 03:09:07
User entered 'Yes (Y)'	System	09 Sep 2020 03:09:07

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:08:55', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'e88cd0d7-545f-4a4a-85b0-2c2825dd9528'	System	09 Sep 2020 03:09:07
User entered '98.5'	System	09 Sep 2020 03:09:07

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:09:01', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'e88cd0d7-545f-4a4a-85b0-2c2825dd9528'	System	09 Sep 2020 03:09:07
User entered 'No (N)'	System	09 Sep 2020 03:09:07

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:09:05', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'e88cd0d7-545f-4a4a-85b0-2c2825dd9528'	System	09 Sep 2020 03:09:07
User entered '08 Sep 2020 22:09'	System	09 Sep 2020 03:09:07

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '08 Sep 2020 16:32'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 2'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:35:21', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bc1dbcb6-45ce-474e-8f8f-796a95d266ca'	System	10 Sep 2020 02:35:39
User entered 'Yes (Y)'	System	10 Sep 2020 02:35:39

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:35:26', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bc1dbcb6-45ce-474e-8f8f-796a95d266ca'	System	10 Sep 2020 02:35:39
User entered '96.8'	System	10 Sep 2020 02:35:39

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:35:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bc1dbcb6-45ce-474e-8f8f-796a95d266ca'	System	10 Sep 2020 02:35:39
User entered 'No (N)'	System	10 Sep 2020 02:35:39

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:35:36', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bc1dbcb6-45ce-474e-8f8f-796a95d266ca'	System	10 Sep 2020 02:35:39
User entered '09 Sep 2020 21:35'	System	10 Sep 2020 02:35:39

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 3'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T07:42:02', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd66548b5-d8a3-42ea-af0a-15f9591a6562'	System	11 Sep 2020 12:42:24
User entered 'Yes (Y)'	System	11 Sep 2020 12:42:24

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T07:42:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd66548b5-d8a3-42ea-af0a-15f9591a6562'	System	11 Sep 2020 12:42:24
User entered '97.0'	System	11 Sep 2020 12:42:24

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T07:42:15', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd66548b5-d8a3-42ea-af0a-15f9591a6562'	System	11 Sep 2020 12:42:24
User entered 'No (N)'	System	11 Sep 2020 12:42:24

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T07:42:22', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd66548b5-d8a3-42ea-af0a-15f9591a6562'	System	11 Sep 2020 12:42:24
User entered '11 Sep 2020 07:42'	System	11 Sep 2020 12:42:24

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 4'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:57:10', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '71a76062-ce01-4cec-96ba-ad3b793bedc0'	System	12 Sep 2020 12:57:27
User entered 'Yes (Y)'	System	12 Sep 2020 12:57:27

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:57:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '71a76062-ce01-4cec-96ba-ad3b793bedc0'	System	12 Sep 2020 12:57:27
User entered '96.1'	System	12 Sep 2020 12:57:27

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:57:20', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '71a76062-ce01-4cec-96ba-ad3b793bedc0'	System	12 Sep 2020 12:57:27
User entered 'No (N)'	System	12 Sep 2020 12:57:27

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:57:23', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '71a76062-ce01-4cec-96ba-ad3b793bedc0'	System	12 Sep 2020 12:57:27
User entered '12 Sep 2020 07:57'	System	12 Sep 2020 12:57:27

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 5'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:56:48', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '078b0747-44e3-4c55-9017-ba51d0c02bb1'	System	13 Sep 2020 03:57:00
User entered 'Yes (Y)'	System	13 Sep 2020 03:57:00

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:56:52', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '078b0747-44e3-4c55-9017-ba51d0c02bb1'	System	13 Sep 2020 03:57:00
User entered '96.3'	System	13 Sep 2020 03:57:00

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:56:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '078b0747-44e3-4c55-9017-ba51d0c02bb1'	System	13 Sep 2020 03:57:00
User entered 'No (N)'	System	13 Sep 2020 03:57:00

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:56:59', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '078b0747-44e3-4c55-9017-ba51d0c02bb1'	System	13 Sep 2020 03:57:00
User entered '12 Sep 2020 22:56'	System	13 Sep 2020 03:57:00

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 6'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-14T10:28:34', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7d3dd2e3-6a4e-4400-91ac-cc5611017922'	System	14 Sep 2020 15:28:55
User entered 'Yes (Y)'	System	14 Sep 2020 15:28:55

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-14T10:28:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7d3dd2e3-6a4e-4400-91ac-cc5611017922'	System	14 Sep 2020 15:28:55
User entered '97.8'	System	14 Sep 2020 15:28:55

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-14T10:28:47', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7d3dd2e3-6a4e-4400-91ac-cc5611017922'	System	14 Sep 2020 15:28:55
User entered 'No (N)'	System	14 Sep 2020 15:28:55

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-14T10:28:50', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7d3dd2e3-6a4e-4400-91ac-cc5611017922'	System	14 Sep 2020 15:28:55
User entered '14 Sep 2020 10:28'	System	14 Sep 2020 15:28:55

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 7'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '13bf9481-b3cd-48cd-a0c6-349c82fb972c'	System	15 Sep 2020 14:46:21
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:21

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:13', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '13bf9481-b3cd-48cd-a0c6-349c82fb972c'	System	15 Sep 2020 14:46:21
User entered '97.4'	System	15 Sep 2020 14:46:21

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:15', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '13bf9481-b3cd-48cd-a0c6-349c82fb972c'	System	15 Sep 2020 14:46:21
User entered 'No (N)'	System	15 Sep 2020 14:46:21

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:18', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '13bf9481-b3cd-48cd-a0c6-349c82fb972c'	System	15 Sep 2020 14:46:21
User entered '15 Sep 2020 09:46'	System	15 Sep 2020 14:46:21

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:24:58', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '334fb5db-8712-465a-83be-3eae6dd5e736'	System	08 Sep 2020 18:25:28
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 18:25:28

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:02', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '334fb5db-8712-465a-83be-3eae6dd5e736'	System	08 Sep 2020 18:25:28
User entered 'No (N)'	System	08 Sep 2020 18:25:28

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:05', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '334fb5db-8712-465a-83be-3eae6dd5e736'	System	08 Sep 2020 18:25:28
User entered 'No (N)'	System	08 Sep 2020 18:25:28

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:18', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '334fb5db-8712-465a-83be-3eae6dd5e736'	System	08 Sep 2020 18:25:28
User entered 'None (1)'	System	08 Sep 2020 18:25:28

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:23', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '334fb5db-8712-465a-83be-3eae6dd5e736'	System	08 Sep 2020 18:25:28
User entered '08 Sep 2020 13:25'	System	08 Sep 2020 18:25:28

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '08 Sep 2020 13:07'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '08 Sep 2020 15:37'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:09:16', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4d2d5b15-d4b2-479f-b6b0-565dd9f879f0'	System	09 Sep 2020 03:10:20
User entered 'None (1)'	System	09 Sep 2020 03:10:20

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:09:46', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4d2d5b15-d4b2-479f-b6b0-565dd9f879f0'	System	09 Sep 2020 03:10:20
User entered 'No (N)'	System	09 Sep 2020 03:10:20

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:09:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4d2d5b15-d4b2-479f-b6b0-565dd9f879f0'	System	09 Sep 2020 03:10:20
User entered 'No (N)'	System	09 Sep 2020 03:10:20

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:10:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4d2d5b15-d4b2-479f-b6b0-565dd9f879f0'	System	09 Sep 2020 03:10:20
User entered 'None (1)'	System	09 Sep 2020 03:10:20

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:10:18', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4d2d5b15-d4b2-479f-b6b0-565dd9f879f0'	System	09 Sep 2020 03:10:20
User entered '08 Sep 2020 22:10'	System	09 Sep 2020 03:10:20

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '08 Sep 2020 16:32'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 2'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:35:47', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '575db1cd-c8fe-4f83-9fa3-201b891fc9c1'	System	10 Sep 2020 02:36:15
User entered 'None (1)'	System	10 Sep 2020 02:36:15

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:35:50', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '575db1cd-c8fe-4f83-9fa3-201b891fc9c1'	System	10 Sep 2020 02:36:15
User entered 'No (N)'	System	10 Sep 2020 02:36:15

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:35:54', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '575db1cd-c8fe-4f83-9fa3-201b891fc9c1'	System	10 Sep 2020 02:36:15
User entered 'No (N)'	System	10 Sep 2020 02:36:15

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:06', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '575db1cd-c8fe-4f83-9fa3-201b891fc9c1'	System	10 Sep 2020 02:36:15
User entered 'None (1)'	System	10 Sep 2020 02:36:15

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:09', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '575db1cd-c8fe-4f83-9fa3-201b891fc9c1'	System	10 Sep 2020 02:36:15
User entered '09 Sep 2020 21:36'	System	10 Sep 2020 02:36:15

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 3'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:53:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7fb6c521-1ed6-4ea5-84ce-f9666c18b1b3'	System	11 Sep 2020 14:53:48
User entered 'None (1)'	System	11 Sep 2020 14:53:48

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:53:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7fb6c521-1ed6-4ea5-84ce-f9666c18b1b3'	System	11 Sep 2020 14:53:48
User entered 'No (N)'	System	11 Sep 2020 14:53:48

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:53:34', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7fb6c521-1ed6-4ea5-84ce-f9666c18b1b3'	System	11 Sep 2020 14:53:48
User entered 'No (N)'	System	11 Sep 2020 14:53:48

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:53:40', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7fb6c521-1ed6-4ea5-84ce-f9666c18b1b3'	System	11 Sep 2020 14:53:48
User entered 'None (1)'	System	11 Sep 2020 14:53:48

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:53:43', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7fb6c521-1ed6-4ea5-84ce-f9666c18b1b3'	System	11 Sep 2020 14:53:48
User entered '11 Sep 2020 09:53'	System	11 Sep 2020 14:53:48

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 4'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:57:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b564a7a7-db2d-41a4-80da-5063f50f236f'	System	12 Sep 2020 12:58:00
User entered 'None (1)'	System	12 Sep 2020 12:58:00

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:57:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b564a7a7-db2d-41a4-80da-5063f50f236f'	System	12 Sep 2020 12:58:00
User entered 'No (N)'	System	12 Sep 2020 12:58:00

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:57:47', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b564a7a7-db2d-41a4-80da-5063f50f236f'	System	12 Sep 2020 12:58:00
User entered 'No (N)'	System	12 Sep 2020 12:58:00

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:57:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b564a7a7-db2d-41a4-80da-5063f50f236f'	System	12 Sep 2020 12:58:00
User entered 'None (1)'	System	12 Sep 2020 12:58:00

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:57:58', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'b564a7a7-db2d-41a4-80da-5063f50f236f'	System	12 Sep 2020 12:58:00
User entered '12 Sep 2020 07:57'	System	12 Sep 2020 12:58:00

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 5'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:04', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a7572e17-6eaa-4777-b691-1c62e4feb309'	System	13 Sep 2020 03:57:19
User entered 'None (1)'	System	13 Sep 2020 03:57:19

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a7572e17-6eaa-4777-b691-1c62e4feb309'	System	13 Sep 2020 03:57:19
User entered 'No (N)'	System	13 Sep 2020 03:57:19

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:10', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a7572e17-6eaa-4777-b691-1c62e4feb309'	System	13 Sep 2020 03:57:19
User entered 'No (N)'	System	13 Sep 2020 03:57:19

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a7572e17-6eaa-4777-b691-1c62e4feb309'	System	13 Sep 2020 03:57:19
User entered 'None (1)'	System	13 Sep 2020 03:57:19

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:17', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a7572e17-6eaa-4777-b691-1c62e4feb309'	System	13 Sep 2020 03:57:19
User entered '12 Sep 2020 22:57'	System	13 Sep 2020 03:57:19

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 6'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-14T10:28:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7d8436f5-5c59-49de-84cb-a8f30957fd5b'	System	14 Sep 2020 15:29:11
User entered 'None (1)'	System	14 Sep 2020 15:29:11

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-14T10:28:59', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7d8436f5-5c59-49de-84cb-a8f30957fd5b'	System	14 Sep 2020 15:29:11
User entered 'No (N)'	System	14 Sep 2020 15:29:11

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-14T10:29:01', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7d8436f5-5c59-49de-84cb-a8f30957fd5b'	System	14 Sep 2020 15:29:11
User entered 'No (N)'	System	14 Sep 2020 15:29:11

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-14T10:29:05', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7d8436f5-5c59-49de-84cb-a8f30957fd5b'	System	14 Sep 2020 15:29:11
User entered 'None (1)'	System	14 Sep 2020 15:29:11

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-14T10:29:09', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7d8436f5-5c59-49de-84cb-a8f30957fd5b'	System	14 Sep 2020 15:29:11
User entered '14 Sep 2020 10:29'	System	14 Sep 2020 15:29:11

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 7'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:21', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1a56e09e-96c0-4226-a23b-d43aa7d45b06'	System	15 Sep 2020 14:46:40
User entered 'None (1)'	System	15 Sep 2020 14:46:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:23', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1a56e09e-96c0-4226-a23b-d43aa7d45b06'	System	15 Sep 2020 14:46:40
User entered 'No (N)'	System	15 Sep 2020 14:46:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:26', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1a56e09e-96c0-4226-a23b-d43aa7d45b06'	System	15 Sep 2020 14:46:40
User entered 'No (N)'	System	15 Sep 2020 14:46:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:34', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1a56e09e-96c0-4226-a23b-d43aa7d45b06'	System	15 Sep 2020 14:46:40
User entered 'None (1)'	System	15 Sep 2020 14:46:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1a56e09e-96c0-4226-a23b-d43aa7d45b06'	System	15 Sep 2020 14:46:40
User entered '15 Sep 2020 09:46'	System	15 Sep 2020 14:46:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c367eaec-1024-48ba-97f5-c81b25d855b3'	System	08 Sep 2020 18:25:57
User entered 'None (0)'	System	08 Sep 2020 18:25:57

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:32', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c367eaec-1024-48ba-97f5-c81b25d855b3'	System	08 Sep 2020 18:25:57
User entered 'None (0)'	System	08 Sep 2020 18:25:57

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c367eaec-1024-48ba-97f5-c81b25d855b3'	System	08 Sep 2020 18:25:57
User entered 'None (0)'	System	08 Sep 2020 18:25:57

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:39', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c367eaec-1024-48ba-97f5-c81b25d855b3'	System	08 Sep 2020 18:25:57
User entered 'None (0)'	System	08 Sep 2020 18:25:57

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:43', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c367eaec-1024-48ba-97f5-c81b25d855b3'	System	08 Sep 2020 18:25:57
User entered 'None (0)'	System	08 Sep 2020 18:25:57

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:46', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c367eaec-1024-48ba-97f5-c81b25d855b3'	System	08 Sep 2020 18:25:57
User entered 'None (0)'	System	08 Sep 2020 18:25:57

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:51', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c367eaec-1024-48ba-97f5-c81b25d855b3'	System	08 Sep 2020 18:25:57
User entered 'No (N)'	System	08 Sep 2020 18:25:57

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T13:25:54', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c367eaec-1024-48ba-97f5-c81b25d855b3'	System	08 Sep 2020 18:25:57
User entered '08 Sep 2020 13:25'	System	08 Sep 2020 18:25:57

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '08 Sep 2020 13:07'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '08 Sep 2020 15:37'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:10:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ba6cddda-c0b0-4dac-9de3-5c117d8808ae'	System	09 Sep 2020 03:11:09
User entered 'None (0)'	System	09 Sep 2020 03:11:09

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:10:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ba6cddda-c0b0-4dac-9de3-5c117d8808ae'	System	09 Sep 2020 03:11:09
User entered 'None (0)'	System	09 Sep 2020 03:11:09

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:10:45', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ba6cddda-c0b0-4dac-9de3-5c117d8808ae'	System	09 Sep 2020 03:11:09
User entered 'None (0)'	System	09 Sep 2020 03:11:09

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:10:49', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ba6cddda-c0b0-4dac-9de3-5c117d8808ae'	System	09 Sep 2020 03:11:09
User entered 'None (0)'	System	09 Sep 2020 03:11:09

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:10:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ba6cddda-c0b0-4dac-9de3-5c117d8808ae'	System	09 Sep 2020 03:11:09
User entered 'None (0)'	System	09 Sep 2020 03:11:09

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:10:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ba6cddda-c0b0-4dac-9de3-5c117d8808ae'	System	09 Sep 2020 03:11:09
User entered 'None (0)'	System	09 Sep 2020 03:11:09

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:11:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ba6cddda-c0b0-4dac-9de3-5c117d8808ae'	System	09 Sep 2020 03:11:09
User entered 'No (N)'	System	09 Sep 2020 03:11:09

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-08T22:11:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ba6cddda-c0b0-4dac-9de3-5c117d8808ae'	System	09 Sep 2020 03:11:09
User entered '08 Sep 2020 22:11'	System	09 Sep 2020 03:11:09

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '08 Sep 2020 16:32'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 2'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:18', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'de078990-6d34-4dc0-8778-20d65f406efe'	System	10 Sep 2020 02:36:53
User entered 'None (0)'	System	10 Sep 2020 02:36:53

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:22', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'de078990-6d34-4dc0-8778-20d65f406efe'	System	10 Sep 2020 02:36:53
User entered 'None (0)'	System	10 Sep 2020 02:36:53

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:26', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'de078990-6d34-4dc0-8778-20d65f406efe'	System	10 Sep 2020 02:36:53
User entered 'None (0)'	System	10 Sep 2020 02:36:53

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:29', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'de078990-6d34-4dc0-8778-20d65f406efe'	System	10 Sep 2020 02:36:53
User entered 'None (0)'	System	10 Sep 2020 02:36:53

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:34', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'de078990-6d34-4dc0-8778-20d65f406efe'	System	10 Sep 2020 02:36:53
User entered 'None (0)'	System	10 Sep 2020 02:36:53

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:39', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'de078990-6d34-4dc0-8778-20d65f406efe'	System	10 Sep 2020 02:36:53
User entered 'None (0)'	System	10 Sep 2020 02:36:53

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'de078990-6d34-4dc0-8778-20d65f406efe'	System	10 Sep 2020 02:36:53
User entered 'No (N)'	System	10 Sep 2020 02:36:53

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-09T21:36:51', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'de078990-6d34-4dc0-8778-20d65f406efe'	System	10 Sep 2020 02:36:53
User entered '09 Sep 2020 21:36'	System	10 Sep 2020 02:36:53

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 3'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:53:49', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bca7e622-8b3c-47a0-806c-1260efb83825'	System	11 Sep 2020 14:54:25
User entered 'None (0)'	System	11 Sep 2020 14:54:25

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:53:54', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bca7e622-8b3c-47a0-806c-1260efb83825'	System	11 Sep 2020 14:54:25
User entered 'No interference with activity (1)'	System	11 Sep 2020 14:54:25

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:54:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bca7e622-8b3c-47a0-806c-1260efb83825'	System	11 Sep 2020 14:54:25
User entered 'No interference with activity (1)'	System	11 Sep 2020 14:54:25

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:54:04', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bca7e622-8b3c-47a0-806c-1260efb83825'	System	11 Sep 2020 14:54:25
User entered 'No interference with activity (1)'	System	11 Sep 2020 14:54:25

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:54:08', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bca7e622-8b3c-47a0-806c-1260efb83825'	System	11 Sep 2020 14:54:25
User entered 'None (0)'	System	11 Sep 2020 14:54:25

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:54:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bca7e622-8b3c-47a0-806c-1260efb83825'	System	11 Sep 2020 14:54:25
User entered 'None (0)'	System	11 Sep 2020 14:54:25

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:54:20', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bca7e622-8b3c-47a0-806c-1260efb83825'	System	11 Sep 2020 14:54:25
User entered 'No (N)'	System	11 Sep 2020 14:54:25

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-11T09:54:22', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bca7e622-8b3c-47a0-806c-1260efb83825'	System	11 Sep 2020 14:54:25
User entered '11 Sep 2020 09:54'	System	11 Sep 2020 14:54:25

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 4'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:58:04', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1fc1d839-ec0b-492c-892d-62a82216303b'	System	12 Sep 2020 12:58:39
User entered 'None (0)'	System	12 Sep 2020 12:58:39

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:58:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1fc1d839-ec0b-492c-892d-62a82216303b'	System	12 Sep 2020 12:58:39
User entered 'No interference with activity (1)'	System	12 Sep 2020 12:58:39

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:58:12', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1fc1d839-ec0b-492c-892d-62a82216303b'	System	12 Sep 2020 12:58:39
User entered 'No interference with activity (1)'	System	12 Sep 2020 12:58:39

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:58:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1fc1d839-ec0b-492c-892d-62a82216303b'	System	12 Sep 2020 12:58:39
User entered 'No interference with activity (1)'	System	12 Sep 2020 12:58:39

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:58:17', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1fc1d839-ec0b-492c-892d-62a82216303b'	System	12 Sep 2020 12:58:39
User entered 'None (0)'	System	12 Sep 2020 12:58:39

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:58:27', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1fc1d839-ec0b-492c-892d-62a82216303b'	System	12 Sep 2020 12:58:39
User entered 'None (0)'	System	12 Sep 2020 12:58:39

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:58:34', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1fc1d839-ec0b-492c-892d-62a82216303b'	System	12 Sep 2020 12:58:39
User entered 'No (N)'	System	12 Sep 2020 12:58:39

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T07:58:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1fc1d839-ec0b-492c-892d-62a82216303b'	System	12 Sep 2020 12:58:39
User entered '12 Sep 2020 07:58'	System	12 Sep 2020 12:58:39

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 5'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:21', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '61d0c99c-10f1-48cd-bd1e-af0f04f8ea01'	System	13 Sep 2020 03:57:48
User entered 'None (0)'	System	13 Sep 2020 03:57:48

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:25', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '61d0c99c-10f1-48cd-bd1e-af0f04f8ea01'	System	13 Sep 2020 03:57:48
User entered 'No interference with activity (1)'	System	13 Sep 2020 03:57:48

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:29', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '61d0c99c-10f1-48cd-bd1e-af0f04f8ea01'	System	13 Sep 2020 03:57:48
User entered 'No interference with activity (1)'	System	13 Sep 2020 03:57:48

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:32', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '61d0c99c-10f1-48cd-bd1e-af0f04f8ea01'	System	13 Sep 2020 03:57:48
User entered 'No interference with activity (1)'	System	13 Sep 2020 03:57:48

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:35', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '61d0c99c-10f1-48cd-bd1e-af0f04f8ea01'	System	13 Sep 2020 03:57:48
User entered 'None (0)'	System	13 Sep 2020 03:57:48

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:39', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '61d0c99c-10f1-48cd-bd1e-af0f04f8ea01'	System	13 Sep 2020 03:57:48
User entered 'None (0)'	System	13 Sep 2020 03:57:48

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:42', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '61d0c99c-10f1-48cd-bd1e-af0f04f8ea01'	System	13 Sep 2020 03:57:48
User entered 'No (N)'	System	13 Sep 2020 03:57:48

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-12T22:57:45', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '61d0c99c-10f1-48cd-bd1e-af0f04f8ea01'	System	13 Sep 2020 03:57:48
User entered '12 Sep 2020 22:57'	System	13 Sep 2020 03:57:48

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 6'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	08 Sep 2020 17:59:40
User entered 'Day 7'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:42', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '095bff52-598b-4de8-82b9-8e95bc4e03f1'	System	15 Sep 2020 14:47:07
User entered 'None (0)'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:45', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '095bff52-598b-4de8-82b9-8e95bc4e03f1'	System	15 Sep 2020 14:47:07
User entered 'No interference with activity (1)'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:48', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '095bff52-598b-4de8-82b9-8e95bc4e03f1'	System	15 Sep 2020 14:47:07
User entered 'No interference with activity (1)'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:52', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '095bff52-598b-4de8-82b9-8e95bc4e03f1'	System	15 Sep 2020 14:47:07
User entered 'No interference with activity (1)'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:55', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '095bff52-598b-4de8-82b9-8e95bc4e03f1'	System	15 Sep 2020 14:47:07
User entered 'None (0)'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:46:57', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '095bff52-598b-4de8-82b9-8e95bc4e03f1'	System	15 Sep 2020 14:47:07
User entered 'None (0)'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:47:01', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '095bff52-598b-4de8-82b9-8e95bc4e03f1'	System	15 Sep 2020 14:47:07
User entered 'No (N)'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-15T09:47:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '095bff52-598b-4de8-82b9-8e95bc4e03f1'	System	15 Sep 2020 14:47:07
User entered '15 Sep 2020 09:47'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:59:40

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	15 Sep 2020 14:47:07
User entered 'Day 8'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-16T10:58:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd651892a-deb0-4fa1-a0a1-0a7bdd2804ec'	System	16 Sep 2020 15:58:15
User entered 'No interference with activity (1)'	System	16 Sep 2020 15:58:15

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-16T10:58:10', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd651892a-deb0-4fa1-a0a1-0a7bdd2804ec'	System	16 Sep 2020 15:58:15
User entered '16 Sep 2020 10:58'	System	16 Sep 2020 15:58:15

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	15 Sep 2020 14:47:07
User entered 'Day 9'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-17T09:29:18', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4b5ff2e3-f334-434c-b23b-4b231259f9b1'	System	17 Sep 2020 14:29:23
User entered 'No interference with activity (1)'	System	17 Sep 2020 14:29:23

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-17T09:29:21', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4b5ff2e3-f334-434c-b23b-4b231259f9b1'	System	17 Sep 2020 14:29:23
User entered '17 Sep 2020 09:29'	System	17 Sep 2020 14:29:23

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	16 Sep 2020 15:58:15
User entered 'Day 10'	System	16 Sep 2020 15:58:15

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-18T09:55:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0bfc4c2c-a1b1-4b02-b48b-e4b69ec2f529'	System	18 Sep 2020 14:56:00
User entered 'No interference with activity (1)'	System	18 Sep 2020 14:56:00

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-18T09:55:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0bfc4c2c-a1b1-4b02-b48b-e4b69ec2f529'	System	18 Sep 2020 14:56:00
User entered '18 Sep 2020 09:55'	System	18 Sep 2020 14:56:00

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:58:15

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:58:15

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	17 Sep 2020 14:29:23
User entered 'Day 11'	System	17 Sep 2020 14:29:23

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-19T10:49:23', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '461042ce-5299-4d33-8f88-07c9f67b9f4f'	System	19 Sep 2020 15:49:29
User entered 'No interference with activity (1)'	System	19 Sep 2020 15:49:29

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-19T10:49:26', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '461042ce-5299-4d33-8f88-07c9f67b9f4f'	System	19 Sep 2020 15:49:29
User entered '19 Sep 2020 10:49'	System	19 Sep 2020 15:49:29

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:29:23

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:29:23

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	18 Sep 2020 14:56:00
User entered 'Day 12'	System	18 Sep 2020 14:56:00

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-20T07:16:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '774f18f4-c85e-4408-94f7-fb0342ea14c7'	System	20 Sep 2020 12:16:50
User entered 'No interference with activity (1)'	System	20 Sep 2020 12:16:50

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-20T07:16:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '774f18f4-c85e-4408-94f7-fb0342ea14c7'	System	20 Sep 2020 12:16:50
User entered '20 Sep 2020 07:16'	System	20 Sep 2020 12:16:50

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:56:00

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:56:00

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	19 Sep 2020 15:49:29
User entered 'Day 13'	System	19 Sep 2020 15:49:29

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-21T09:37:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '929770d0-7084-40b8-b418-d1dcd31c79af'	System	21 Sep 2020 14:37:17
User entered 'No interference with activity (1)'	System	21 Sep 2020 14:37:17

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-21T09:37:10', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '929770d0-7084-40b8-b418-d1dcd31c79af'	System	21 Sep 2020 14:37:17
User entered '21 Sep 2020 09:37'	System	21 Sep 2020 14:37:17

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 15:49:29

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 15:49:29

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	20 Sep 2020 12:16:50
User entered 'Day 14'	System	20 Sep 2020 12:16:50

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-22T06:46:54', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0aad8c06-1256-4cf2-a336-b217add56209'	System	22 Sep 2020 11:46:58
User entered 'No interference with activity (1)'	System	22 Sep 2020 11:46:58

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-22T06:46:56', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0aad8c06-1256-4cf2-a336-b217add56209'	System	22 Sep 2020 11:46:58
User entered '22 Sep 2020 06:46'	System	22 Sep 2020 11:46:58

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 12:16:50

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 12:16:50

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	21 Sep 2020 14:37:17
User entered 'Day 15'	System	21 Sep 2020 14:37:17

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:37:17

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:37:17

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	22 Sep 2020 11:46:58
User entered 'Day 16'	System	22 Sep 2020 11:46:58

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-24T06:53:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '8df57ca3-3a5e-41ed-a267-b8873d8d7939'	System	24 Sep 2020 11:53:52
User entered 'No interference with activity (1)'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-24T06:53:48', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '8df57ca3-3a5e-41ed-a267-b8873d8d7939'	System	24 Sep 2020 11:53:52
User entered '24 Sep 2020 06:53'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 11:46:58

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 11:46:58

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	24 Sep 2020 11:53:52
User entered 'Day 17'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	24 Sep 2020 11:53:52
User entered 'Day 18'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	15 Sep 2020 14:47:07
User entered 'Day 8'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-16T10:58:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ab96fa88-c555-4400-9dec-61e68bc1451c'	System	16 Sep 2020 15:58:23
User entered 'No interference with activity (1)'	System	16 Sep 2020 15:58:23

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-16T10:58:17', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ab96fa88-c555-4400-9dec-61e68bc1451c'	System	16 Sep 2020 15:58:23
User entered '16 Sep 2020 10:58'	System	16 Sep 2020 15:58:23

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	15 Sep 2020 14:47:07
User entered 'Day 9'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-17T09:29:26', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '8f239874-0611-4831-9c12-6565e8e898e7'	System	17 Sep 2020 14:29:31
User entered 'No interference with activity (1)'	System	17 Sep 2020 14:29:31

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-17T09:29:29', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '8f239874-0611-4831-9c12-6565e8e898e7'	System	17 Sep 2020 14:29:31
User entered '17 Sep 2020 09:29'	System	17 Sep 2020 14:29:31

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	16 Sep 2020 15:58:23
User entered 'Day 10'	System	16 Sep 2020 15:58:23

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-18T09:55:59', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0904d90f-b65b-4d42-b56a-60c1f30a45a9'	System	18 Sep 2020 14:56:05
User entered 'No interference with activity (1)'	System	18 Sep 2020 14:56:05

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-18T09:56:01', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0904d90f-b65b-4d42-b56a-60c1f30a45a9'	System	18 Sep 2020 14:56:05
User entered '18 Sep 2020 09:56'	System	18 Sep 2020 14:56:05

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:58:23

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:58:23

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	17 Sep 2020 14:29:31
User entered 'Day 11'	System	17 Sep 2020 14:29:31

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-19T10:49:29', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7ba0237b-08bf-46d8-9186-e5935a03ab62'	System	19 Sep 2020 15:49:36
User entered 'No interference with activity (1)'	System	19 Sep 2020 15:49:36

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-19T10:49:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7ba0237b-08bf-46d8-9186-e5935a03ab62'	System	19 Sep 2020 15:49:36
User entered '19 Sep 2020 10:49'	System	19 Sep 2020 15:49:36

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:29:31

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:29:31

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	18 Sep 2020 14:56:05
User entered 'Day 12'	System	18 Sep 2020 14:56:05

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-20T07:16:48', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '23d759a9-035e-40e1-9370-9700eb21e33b'	System	20 Sep 2020 12:16:51
User entered 'No interference with activity (1)'	System	20 Sep 2020 12:16:51

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-20T07:16:50', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '23d759a9-035e-40e1-9370-9700eb21e33b'	System	20 Sep 2020 12:16:51
User entered '20 Sep 2020 07:16'	System	20 Sep 2020 12:16:51

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:56:05

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:56:05

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	19 Sep 2020 15:49:36
User entered 'Day 13'	System	19 Sep 2020 15:49:36

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-21T09:37:20', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c43a349b-c618-44d3-b7fb-8231f65751af'	System	21 Sep 2020 14:37:29
User entered 'No interference with activity (1)'	System	21 Sep 2020 14:37:29

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-21T09:37:24', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c43a349b-c618-44d3-b7fb-8231f65751af'	System	21 Sep 2020 14:37:29
User entered '21 Sep 2020 09:37'	System	21 Sep 2020 14:37:29

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 15:49:36

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 15:49:36

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	20 Sep 2020 12:16:51
User entered 'Day 14'	System	20 Sep 2020 12:16:51

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-22T06:47:01', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '9f8aef2c-975b-4282-842f-e54492511a0d'	System	22 Sep 2020 11:47:08
User entered 'No interference with activity (1)'	System	22 Sep 2020 11:47:08

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-22T06:47:04', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '9f8aef2c-975b-4282-842f-e54492511a0d'	System	22 Sep 2020 11:47:08
User entered '22 Sep 2020 06:47'	System	22 Sep 2020 11:47:08

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 12:16:51

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 12:16:51

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	21 Sep 2020 14:37:29
User entered 'Day 15'	System	21 Sep 2020 14:37:29

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:37:29

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:37:29

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	22 Sep 2020 11:47:08
User entered 'Day 16'	System	22 Sep 2020 11:47:08

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-24T06:53:52', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '56e2d60a-1bcb-4005-ad4e-68fc3fe9046c'	System	24 Sep 2020 11:54:00
User entered 'No interference with activity (1)'	System	24 Sep 2020 11:54:00

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-24T06:53:54', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '56e2d60a-1bcb-4005-ad4e-68fc3fe9046c'	System	24 Sep 2020 11:54:00
User entered '24 Sep 2020 06:53'	System	24 Sep 2020 11:54:00

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 11:47:08

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 11:47:08

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	24 Sep 2020 11:54:00
User entered 'Day 17'	System	24 Sep 2020 11:54:00

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 11:54:00

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 11:54:00

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	24 Sep 2020 11:54:00
User entered 'Day 18'	System	24 Sep 2020 11:54:00

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 11:54:00

US3032187

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 11:54:00

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	15 Sep 2020 14:47:07
User entered 'Day 8'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-16T10:58:22', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bf683962-da29-49b2-bd3a-7ea6e30874cf'	System	16 Sep 2020 15:58:28
User entered 'No interference with activity (1)'	System	16 Sep 2020 15:58:28

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-16T10:58:24', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'bf683962-da29-49b2-bd3a-7ea6e30874cf'	System	16 Sep 2020 15:58:28
User entered '16 Sep 2020 10:58'	System	16 Sep 2020 15:58:28

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	15 Sep 2020 14:47:07
User entered 'Day 9'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-17T09:29:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5c24943c-8523-46a8-b819-1444993157ce'	System	17 Sep 2020 14:29:39
User entered 'No interference with activity (1)'	System	17 Sep 2020 14:29:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-17T09:29:36', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5c24943c-8523-46a8-b819-1444993157ce'	System	17 Sep 2020 14:29:39
User entered '17 Sep 2020 09:29'	System	17 Sep 2020 14:29:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	16 Sep 2020 15:58:28
User entered 'Day 10'	System	16 Sep 2020 15:58:28

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-18T09:56:05', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6124da57-c9d2-48e3-93ca-01af2faff868'	System	18 Sep 2020 14:56:09
User entered 'No interference with activity (1)'	System	18 Sep 2020 14:56:09

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-18T09:56:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6124da57-c9d2-48e3-93ca-01af2faff868'	System	18 Sep 2020 14:56:09
User entered '18 Sep 2020 09:56'	System	18 Sep 2020 14:56:09

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:58:28

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:58:28

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	17 Sep 2020 14:29:39
User entered 'Day 11'	System	17 Sep 2020 14:29:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-19T10:49:34', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '21dc6240-1c6b-4cb2-a0c8-b9217846563c'	System	19 Sep 2020 15:49:39
User entered 'No interference with activity (1)'	System	19 Sep 2020 15:49:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-19T10:49:36', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '21dc6240-1c6b-4cb2-a0c8-b9217846563c'	System	19 Sep 2020 15:49:39
User entered '19 Sep 2020 10:49'	System	19 Sep 2020 15:49:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:29:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:29:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	18 Sep 2020 14:56:09
User entered 'Day 12'	System	18 Sep 2020 14:56:09

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-20T07:16:54', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'abe053e2-02fb-4788-ac8c-894c030bab89'	System	20 Sep 2020 12:16:57
User entered 'No interference with activity (1)'	System	20 Sep 2020 12:16:57

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-20T07:16:55', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'abe053e2-02fb-4788-ac8c-894c030bab89'	System	20 Sep 2020 12:16:57
User entered '20 Sep 2020 07:16'	System	20 Sep 2020 12:16:57

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:56:09

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:56:09

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	19 Sep 2020 15:49:39
User entered 'Day 13'	System	19 Sep 2020 15:49:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-21T09:37:36', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f726234f-81ad-4290-bf4b-e792f4339525'	System	21 Sep 2020 14:37:43
User entered 'No interference with activity (1)'	System	21 Sep 2020 14:37:43

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-21T09:37:38', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f726234f-81ad-4290-bf4b-e792f4339525'	System	21 Sep 2020 14:37:43
User entered '21 Sep 2020 09:37'	System	21 Sep 2020 14:37:43

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 15:49:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 15:49:39

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	20 Sep 2020 12:16:57
User entered 'Day 14'	System	20 Sep 2020 12:16:57

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-22T06:47:08', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'fe610b87-9399-418a-a247-8361f09b999d'	System	22 Sep 2020 11:47:14
User entered 'No interference with activity (1)'	System	22 Sep 2020 11:47:14

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-22T06:47:11', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'fe610b87-9399-418a-a247-8361f09b999d'	System	22 Sep 2020 11:47:14
User entered '22 Sep 2020 06:47'	System	22 Sep 2020 11:47:14

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 12:16:57

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 12:16:57

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	21 Sep 2020 14:37:43
User entered 'Day 15'	System	21 Sep 2020 14:37:43

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:37:43

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:37:43

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	22 Sep 2020 11:47:14
User entered 'Day 16'	System	22 Sep 2020 11:47:14

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-24T06:53:58', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'cd1fd562-81ab-4abc-abc6-d978d9d3cc2c'	System	24 Sep 2020 11:54:05
User entered 'No interference with activity (1)'	System	24 Sep 2020 11:54:05

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-24T06:54:01', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'cd1fd562-81ab-4abc-abc6-d978d9d3cc2c'	System	24 Sep 2020 11:54:05
User entered '24 Sep 2020 06:54'	System	24 Sep 2020 11:54:05

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 11:47:14

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 11:47:14

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	24 Sep 2020 11:54:05
User entered 'Day 17'	System	24 Sep 2020 11:54:05

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 11:54:05

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 11:54:05

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	24 Sep 2020 11:54:05
User entered 'Day 18'	System	24 Sep 2020 11:54:05

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 11:54:05

US3032187

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 11:54:05

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	15 Sep 2020 14:47:07
User entered 'Day 8'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-16T10:58:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7bfeff65-7a4a-4fa5-aba3-3e407ae22980'	System	16 Sep 2020 15:58:37
User entered 'No (N)'	System	16 Sep 2020 15:58:37

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-16T10:58:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '7bfeff65-7a4a-4fa5-aba3-3e407ae22980'	System	16 Sep 2020 15:58:37
User entered '16 Sep 2020 10:58'	System	16 Sep 2020 15:58:37

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	15 Sep 2020 14:47:07
User entered 'Day 9'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-17T09:29:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c5691339-8877-427f-8b9d-0c594f0e0026'	System	17 Sep 2020 14:29:48
User entered 'No (N)'	System	17 Sep 2020 14:29:48

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-17T09:29:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c5691339-8877-427f-8b9d-0c594f0e0026'	System	17 Sep 2020 14:29:48
User entered '17 Sep 2020 09:29'	System	17 Sep 2020 14:29:48

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 14:47:07

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	16 Sep 2020 15:58:15
User entered 'Day 10'	System	16 Sep 2020 15:58:15

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-18T09:56:11', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f64edb60-ad72-4351-a772-a625bb0eeb31'	System	18 Sep 2020 14:56:17
User entered 'No (N)'	System	18 Sep 2020 14:56:17

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-18T09:56:13', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f64edb60-ad72-4351-a772-a625bb0eeb31'	System	18 Sep 2020 14:56:17
User entered '18 Sep 2020 09:56'	System	18 Sep 2020 14:56:17

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:58:15

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:58:15

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	17 Sep 2020 14:29:23
User entered 'Day 11'	System	17 Sep 2020 14:29:23

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-19T10:49:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '17e4d3c8-f030-4e11-8824-c11e4f66120f'	System	19 Sep 2020 15:49:46
User entered 'No (N)'	System	19 Sep 2020 15:49:46

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-19T10:49:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '17e4d3c8-f030-4e11-8824-c11e4f66120f'	System	19 Sep 2020 15:49:46
User entered '19 Sep 2020 10:49'	System	19 Sep 2020 15:49:46

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:29:23

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:29:23

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	18 Sep 2020 14:56:00
User entered 'Day 12'	System	18 Sep 2020 14:56:00

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-20T07:17:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1e6f3916-a377-4c46-ade0-086f514ffbb'	System	20 Sep 2020 12:17:04
User entered 'No (N)'	System	20 Sep 2020 12:17:04

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-20T07:17:02', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1e6f3916-a377-4c46-ade0-086f514ffbb'	System	20 Sep 2020 12:17:04
User entered '20 Sep 2020 07:17'	System	20 Sep 2020 12:17:04

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:56:00

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:56:00

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	19 Sep 2020 15:49:29
User entered 'Day 13'	System	19 Sep 2020 15:49:29

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-21T09:37:43', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '74f35755-a699-47bd-90ec-ed2b0c13ccc9'	System	21 Sep 2020 14:37:50
User entered 'No (N)'	System	21 Sep 2020 14:37:50

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-21T09:37:47', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '74f35755-a699-47bd-90ec-ed2b0c13ccc9'	System	21 Sep 2020 14:37:50
User entered '21 Sep 2020 09:37'	System	21 Sep 2020 14:37:50

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 15:49:29

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 15:49:29

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	20 Sep 2020 12:16:50
User entered 'Day 14'	System	20 Sep 2020 12:16:50

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-22T06:47:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd744fa80-d922-4008-a2fc-fba7c1dd6b0e'	System	22 Sep 2020 11:47:20
User entered 'No (N)'	System	22 Sep 2020 11:47:20

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-22T06:47:16', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'd744fa80-d922-4008-a2fc-fba7c1dd6b0e'	System	22 Sep 2020 11:47:20
User entered '22 Sep 2020 06:47'	System	22 Sep 2020 11:47:20

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 12:16:50

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 12:16:50

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	21 Sep 2020 14:37:17
User entered 'Day 15'	System	21 Sep 2020 14:37:17

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:37:17

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:37:17

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	22 Sep 2020 11:46:58
User entered 'Day 16'	System	22 Sep 2020 11:46:58

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-24T06:54:04', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '77e87a9b-3d3d-498a-93c9-6b71408d2cd9'	System	24 Sep 2020 11:54:11
User entered 'No (N)'	System	24 Sep 2020 11:54:11

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-09-24T06:54:06', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '77e87a9b-3d3d-498a-93c9-6b71408d2cd9'	System	24 Sep 2020 11:54:11
User entered '24 Sep 2020 06:54'	System	24 Sep 2020 11:54:11

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 11:46:58

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 11:46:58

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	24 Sep 2020 11:53:52
User entered 'Day 17'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	24 Sep 2020 11:53:52
User entered 'Day 18'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:15

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 11:53:52

US3032187

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 14:50:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 11:53:52

US3032187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:00:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	15 Sep 2020 14:53:06

US3032187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:00:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '15 Sep 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	15 Sep 2020 14:53:06

US3032187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:00:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	15 Sep 2020 14:53:06

US3032187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:00:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	15 Sep 2020 14:53:06

US3032187

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:00:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	15 Sep 2020 14:53:11

US3032187

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'I'	System	15 Sep 2020 14:53:11

US3032187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:01:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	24 Sep 2020 00:23:22

US3032187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:01:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '23 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	24 Sep 2020 00:23:22

US3032187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:01:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	24 Sep 2020 00:23:22

US3032187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:01:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	24 Sep 2020 00:23:22

US3032187

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
DataPoint Verified.		09 Mar 2021 18:01:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	24 Sep 2020 00:23:24

US3032187

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'I'	System	24 Sep 2020 00:23:24

US3032187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:56:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:54:41

US3032187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:56:14
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:54:41

US3032187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:56:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:54:41

US3032187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:56:14
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:54:41

US3032187

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:56:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:54:44

US3032187

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'I'	System	29 Sep 2020 20:54:44

US3032187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:24:52

US3032187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '6 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:24:52

US3032187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 21:24:52

US3032187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'VISIT3'	System	06 Oct 2020 21:24:52

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '6 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '13:01'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered '6 Oct 2020 13:01'	System	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '75'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'bpm'	System	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'breaths/min'	System	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '136'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'mmHg'	System	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '87'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'mmHg'	System	06 Oct 2020 21:25:07

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37

US3032187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37

US3032187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:11

US3032187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '6 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:25:11

US3032187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:27:27

US3032187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '6 Oct 2020'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:27:27
	(b) (4)	

US3032187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered '13:15'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:27:27

US3032187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered '6 Oct 2020 13:15'	System	06 Oct 2020 21:27:27

US3032187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:33:21
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 21:27:33

US3032187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:37
User entered 'I'	System	06 Oct 2020 21:27:33

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 64'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-12T12:31:15', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '47145777-18f2-4c17-8431-cee845a6dbd6'	System	12 Oct 2020 17:31:44
User entered 'No (N)'	System	12 Oct 2020 17:31:44

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-12T12:31:34', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '47145777-18f2-4c17-8431-cee845a6dbd6'	System	12 Oct 2020 17:31:44
User entered 'No (N)'	System	12 Oct 2020 17:31:44

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-12T12:31:40', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '47145777-18f2-4c17-8431-cee845a6dbd6'	System	12 Oct 2020 17:31:44
User entered '12 Oct 2020 12:31:40'	System	12 Oct 2020 17:31:44

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 71'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-18T09:28:06', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '537f4c1e-ba75-44cc-b1f4-24cb72d67617'	System	18 Oct 2020 14:30:13
User entered 'No (N)'	System	18 Oct 2020 14:30:13

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-18T09:28:14', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '537f4c1e-ba75-44cc-b1f4-24cb72d67617'	System	18 Oct 2020 14:30:13
User entered 'Yes (Y)'	System	18 Oct 2020 14:30:13

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-18T09:29:59', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '537f4c1e-ba75-44cc-b1f4-24cb72d67617'	System	18 Oct 2020 14:30:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Oct 2020 14:30:13

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-18T09:30:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '537f4c1e-ba75-44cc-b1f4-24cb72d67617' User entered '18 Oct 2020 09:30:03'	System	18 Oct 2020 14:30:13
	System	18 Oct 2020 14:30:13

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 78'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-26T20:14:51', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '694fa6fb-e2a5-416a-a650-fc41713d2708'	System	27 Oct 2020 01:15:10
User entered 'No (N)'	System	27 Oct 2020 01:15:10

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-26T20:14:59', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '694fa6fb-e2a5-416a-a650-fc41713d2708'	System	27 Oct 2020 01:15:10
User entered 'No (N)'	System	27 Oct 2020 01:15:10

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-10-26T20:15:03', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '694fa6fb-e2a5-416a-a650-fc41713d2708'	System	27 Oct 2020 01:15:10
User entered '26 Oct 2020 20:15:03'	System	27 Oct 2020 01:15:10

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 92'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-08T08:17:40', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0792d591-7ae8-434f-a1d4-0f13e8abcc02'	System	08 Nov 2020 14:17:55
User entered 'No (N)'	System	08 Nov 2020 14:17:55

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-08T08:17:46', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0792d591-7ae8-434f-a1d4-0f13e8abcc02'	System	08 Nov 2020 14:17:55
User entered 'No (N)'	System	08 Nov 2020 14:17:55

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-08T08:17:51', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0792d591-7ae8-434f-a1d4-0f13e8abcc02'	System	08 Nov 2020 14:17:55
User entered '08 Nov 2020 08:17:51'	System	08 Nov 2020 14:17:55

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered 'Day 99'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-16T14:08:17', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'cbca2904-e571-4fd4-b8f6-f3251678e5a5'	System	16 Nov 2020 20:08:28
User entered 'No (N)'	System	16 Nov 2020 20:08:28

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-16T14:08:22', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'cbca2904-e571-4fd4-b8f6-f3251678e5a5'	System	16 Nov 2020 20:08:28
User entered 'No (N)'	System	16 Nov 2020 20:08:28

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-16T14:08:24', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'cbca2904-e571-4fd4-b8f6-f3251678e5a5'	System	16 Nov 2020 20:08:28
User entered '16 Nov 2020 14:08:24'	System	16 Nov 2020 20:08:28

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 20:02:39

US3032187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:43:03
Data entry locked.	System	11 Aug 2020 20:02:39
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 20:02:39

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-21T16:15:52', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6aedabb3-5cf6-4978-9a68-cbd236338dc2'	System	21 Nov 2020 22:16:07
User entered 'No (N)'	System	21 Nov 2020 22:16:07

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-21T16:15:58', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6aedabb3-5cf6-4978-9a68-cbd236338dc2'	System	21 Nov 2020 22:16:07
User entered 'No (N)'	System	21 Nov 2020 22:16:07

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-21T16:16:01', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6aedabb3-5cf6-4978-9a68-cbd236338dc2' User entered '21 Nov 2020 16:16:01'	System	21 Nov 2020 22:16:07
	System	21 Nov 2020 22:16:07

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-26T17:11:35', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f28e84a8-aeb2-4744-a690-857eb5fb76a9'	System	26 Nov 2020 23:11:41
User entered 'No (N)'	System	26 Nov 2020 23:11:41

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-26T17:11:32', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f28e84a8-aeb2-4744-a690-857eb5fb76a9'	System	26 Nov 2020 23:11:41
User entered 'No (N)'	System	26 Nov 2020 23:11:41

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-11-26T17:11:39', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'f28e84a8-aeb2-4744-a690-857eb5fb76a9' User entered '26 Nov 2020 17:11:39'	System	26 Nov 2020 23:11:41
	System	26 Nov 2020 23:11:41

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:11', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered 'Yes (Y)'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered 'No (N)'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered 'Yes (Y)'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered '1'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered '1'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb' User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb' User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered '1'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered '1'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb' User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb' User entered '0'	System	07 Dec 2020 18:12:26
	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb' User entered '0'	System	07 Dec 2020 18:12:26
	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb' User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb' User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:11:53', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb' User entered '0'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:12:01', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:12:08', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered 'Yes (Y)'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:12:12', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb'	System	07 Dec 2020 18:12:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-07T12:12:16', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '36c92c41-e9dd-4ab9-beb2-d6ec40e0d1cb' User entered '07 Dec 2020 12:12:16'	System	07 Dec 2020 18:12:26
	System	07 Dec 2020 18:12:26

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-11T15:00:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1e3b327d-b80a-426d-a5a0-28e6b1878a64'	System	11 Dec 2020 21:00:42
User entered 'No (N)'	System	11 Dec 2020 21:00:42

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-11T15:00:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1e3b327d-b80a-426d-a5a0-28e6b1878a64'	System	11 Dec 2020 21:00:42
User entered 'No (N)'	System	11 Dec 2020 21:00:42

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-11T15:00:40', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '1e3b327d-b80a-426d-a5a0-28e6b1878a64'	System	11 Dec 2020 21:00:42
User entered '11 Dec 2020 15:00:40'	System	11 Dec 2020 21:00:42

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-20T18:08:44', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '52704af5-b63b-431a-ba38-46e739dfe6ef'	System	21 Dec 2020 00:08:55
User entered 'No (N)'	System	21 Dec 2020 00:08:55

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-20T18:08:49', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '52704af5-b63b-431a-ba38-46e739dfe6ef'	System	21 Dec 2020 00:08:55
User entered 'No (N)'	System	21 Dec 2020 00:08:55

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-20T18:08:52', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '52704af5-b63b-431a-ba38-46e739dfe6ef' User entered '20 Dec 2020 18:08:52'	System	21 Dec 2020 00:08:55
	System	21 Dec 2020 00:08:55

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-24T11:24:02', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0bfb7312-2f64-4e4c-93d4-23aa36c8c68a'	System	24 Dec 2020 17:24:09
User entered 'No (N)'	System	24 Dec 2020 17:24:09

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-24T11:24:05', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0bfb7312-2f64-4e4c-93d4-23aa36c8c68a'	System	24 Dec 2020 17:24:09
User entered 'No (N)'	System	24 Dec 2020 17:24:09

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2020-12-24T11:24:07', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0bfb7312-2f64-4e4c-93d4-23aa36c8c68a'	System	24 Dec 2020 17:24:09
User entered '24 Dec 2020 11:24:07'	System	24 Dec 2020 17:24:09

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-01-04T08:34:47', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c84d242e-1113-42b7-96fb-44f75d00db18'	System	04 Jan 2021 14:34:58
User entered 'No (N)'	System	04 Jan 2021 14:34:58

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-01-04T08:34:50', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c84d242e-1113-42b7-96fb-44f75d00db18'	System	04 Jan 2021 14:34:58
User entered 'No (N)'	System	04 Jan 2021 14:34:58

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-01-04T08:34:54', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c84d242e-1113-42b7-96fb-44f75d00db18'	System	04 Jan 2021 14:34:58
User entered '04 Jan 2021 08:34:54'	System	04 Jan 2021 14:34:58

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-01-18T18:16:25', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4569c5c1-0a86-432c-8e57-df27175d9f44'	System	19 Jan 2021 00:16:34
User entered 'No (N)'	System	19 Jan 2021 00:16:34

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-01-18T18:16:28', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4569c5c1-0a86-432c-8e57-df27175d9f44'	System	19 Jan 2021 00:16:34
User entered 'No (N)'	System	19 Jan 2021 00:16:34

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-01-18T18:16:31', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '4569c5c1-0a86-432c-8e57-df27175d9f44'	System	19 Jan 2021 00:16:34
User entered '18 Jan 2021 18:16:31'	System	19 Jan 2021 00:16:34

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-01T16:27:34', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ddad71a9-13f4-4e5a-9db7-d8776affcfbd'	System	01 Feb 2021 22:27:43
User entered 'No (N)'	System	01 Feb 2021 22:27:43

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-01T16:27:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ddad71a9-13f4-4e5a-9db7-d8776affcfbd'	System	01 Feb 2021 22:27:43
User entered 'No (N)'	System	01 Feb 2021 22:27:43

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-01T16:27:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'ddad71a9-13f4-4e5a-9db7-d8776affcfbd'	System	01 Feb 2021 22:27:43
User entered '01 Feb 2021 16:27:41'	System	01 Feb 2021 22:27:43

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-04T06:45:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '09fa5707-ac02-4374-847d-a6ceeeb55d43'	System	04 Feb 2021 12:45:43
User entered 'No (N)'	System	04 Feb 2021 12:45:43

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-04T06:45:36', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '09fa5707-ac02-4374-847d-a6ceeb55d43'	System	04 Feb 2021 12:45:43
User entered 'No (N)'	System	04 Feb 2021 12:45:43

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-04T06:45:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '09fa5707-ac02-4374-847d-a6ceeb55d43'	System	04 Feb 2021 12:45:43
User entered '04 Feb 2021 06:45:41'	System	04 Feb 2021 12:45:43

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-11T09:00:30', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'e239b6b5-eaed-449a-93b1-d75e8a24d35e'	System	11 Feb 2021 15:00:38
User entered 'No (N)'	System	11 Feb 2021 15:00:38

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-11T09:00:33', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'e239b6b5-eaed-449a-93b1-d75e8a24d35e'	System	11 Feb 2021 15:00:38
User entered 'No (N)'	System	11 Feb 2021 15:00:38

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-11T09:00:37', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'e239b6b5-eaed-449a-93b1-d75e8a24d35e' User entered '11 Feb 2021 09:00:37'	System	11 Feb 2021 15:00:38
	System	11 Feb 2021 15:00:38

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-19T06:55:41', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '62c0b43e-db46-4a94-b89f-3ae0e06dc190'	System	19 Feb 2021 12:55:50
User entered 'No (N)'	System	19 Feb 2021 12:55:50

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-19T06:55:45', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '62c0b43e-db46-4a94-b89f-3ae0e06dc190'	System	19 Feb 2021 12:55:50
User entered 'No (N)'	System	19 Feb 2021 12:55:50

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-19T06:55:49', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '62c0b43e-db46-4a94-b89f-3ae0e06dc190'	System	19 Feb 2021 12:55:50
User entered '19 Feb 2021 06:55:49'	System	19 Feb 2021 12:55:50

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-25T09:00:23-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5734dc21-daac-4df2-9a8c-7685a9e187d6'	System	25 Feb 2021 15:00:33
User entered 'No (N)'	System	25 Feb 2021 15:00:33

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-25T09:00:25-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5734dc21-daac-4df2-9a8c-7685a9e187d6'	System	25 Feb 2021 15:00:33
User entered 'No (N)'	System	25 Feb 2021 15:00:33

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-02-25T09:00:28-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '5734dc21-daac-4df2-9a8c-7685a9e187d6'	System	25 Feb 2021 15:00:33
User entered '25 Feb 2021 09:00:28'	System	25 Feb 2021 15:00:33

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-07T18:29:59-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '052edfa8-03b6-49f1-9b94-cf43bc151c21'	System	08 Mar 2021 00:30:09
User entered 'No (N)'	System	08 Mar 2021 00:30:09

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-07T18:30:01-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '052edfa8-03b6-49f1-9b94-cf43bc151c21'	System	08 Mar 2021 00:30:09
User entered 'No (N)'	System	08 Mar 2021 00:30:09

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-07T18:30:06-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '052edfa8-03b6-49f1-9b94-cf43bc151c21'	System	08 Mar 2021 00:30:09
User entered '07 Mar 2021 18:30:06'	System	08 Mar 2021 00:30:09

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-11T00:01:34-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6148d4ed-5a3e-43d7-8eb9-76d506444b26'	System	11 Mar 2021 06:01:44
User entered 'No (N)'	System	11 Mar 2021 06:01:44

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-11T00:01:37-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6148d4ed-5a3e-43d7-8eb9-76d506444b26'	System	11 Mar 2021 06:01:44
User entered 'No (N)'	System	11 Mar 2021 06:01:44

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-11T00:01:42-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6148d4ed-5a3e-43d7-8eb9-76d506444b26'	System	11 Mar 2021 06:01:44
User entered '11 Mar 2021 00:01:42'	System	11 Mar 2021 06:01:44

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-21T09:20:30-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0c61c832-3f28-4235-b4a3-28ae73fee93e'	System	21 Mar 2021 14:21:12
User entered 'Yes (Y)'	System	21 Mar 2021 14:21:12

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-21T09:20:37-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0c61c832-3f28-4235-b4a3-28ae73fee93e'	System	21 Mar 2021 14:21:12
User entered 'No (N)'	System	21 Mar 2021 14:21:12

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-21T09:20:42-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0c61c832-3f28-4235-b4a3-28ae73fee93e'	System	21 Mar 2021 14:21:12
User entered 'No (N)'	System	21 Mar 2021 14:21:12

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-21T09:20:47-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0c61c832-3f28-4235-b4a3-28ae73fee93e'	System	21 Mar 2021 14:21:12
User entered 'Yes (Y)'	System	21 Mar 2021 14:21:12

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-21T09:20:58-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0c61c832-3f28-4235-b4a3-28ae73fee93e'	System	21 Mar 2021 14:21:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Mar 2021 14:21:12

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-21T09:21:03-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '0c61c832-3f28-4235-b4a3-28ae73fee93e' User entered '21 Mar 2021 09:21:03'	System	21 Mar 2021 14:21:12
	System	21 Mar 2021 14:21:12

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-04-02T13:05:05-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '204e0e58-8c74-4698-b47e-ac4f1c70f2e4'	System	02 Apr 2021 18:05:15
User entered 'No (N)'	System	02 Apr 2021 18:05:15

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-04-02T13:05:08-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '204e0e58-8c74-4698-b47e-ac4f1c70f2e4'	System	02 Apr 2021 18:05:15
User entered 'No (N)'	System	02 Apr 2021 18:05:15

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-04-02T13:05:10-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '204e0e58-8c74-4698-b47e-ac4f1c70f2e4'	System	02 Apr 2021 18:05:15
User entered '02 Apr 2021 13:05:10'	System	02 Apr 2021 18:05:15

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-04-15T06:38:04-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6c485cc2-b38b-4e2b-94d6-9dcdb186fe2d' User entered 'No (N)'	System	15 Apr 2021 11:38:15

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-04-15T06:38:09-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6c485cc2-b38b-4e2b-94d6-9dcdb186fe2d' User entered 'No (N)'	System	15 Apr 2021 11:38:15

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-04-15T06:38:12-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '6c485cc2-b38b-4e2b-94d6-9dcdb186fe2d' User entered '15 Apr 2021 06:38:12'	System	15 Apr 2021 11:38:15
	System	15 Apr 2021 11:38:15

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-04-25T18:00:06-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c272861e-2b4b-49ab-b7b9-866b692ff5ce' User entered 'No (N)'	System	25 Apr 2021 23:00:18
	System	25 Apr 2021 23:00:18

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-04-25T18:00:10-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c272861e-2b4b-49ab-b7b9-866b692ff5ce' User entered 'No (N)'	System	25 Apr 2021 23:00:18

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-04-25T18:00:15-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'c272861e-2b4b-49ab-b7b9-866b692ff5ce'	System	25 Apr 2021 23:00:18
User entered '25 Apr 2021 18:00:15'	System	25 Apr 2021 23:00:18

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-05-01T12:00:14-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '26279442-e68c-4ee6-8f87-8ccc49425e69' User entered 'No (N)'	System	01 May 2021 17:00:23

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-05-01T12:00:16-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '26279442-e68c-4ee6-8f87-8ccc49425e69'	System	01 May 2021 17:00:23
User entered 'No (N)'	System	01 May 2021 17:00:23

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-05-01T12:00:19-05:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: '26279442-e68c-4ee6-8f87-8ccc49425e69'	System	01 May 2021 17:00:23
User entered '01 May 2021 12:00:19'	System	01 May 2021 17:00:23

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:10:22

US3032187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:10:22
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:10:22

US3032187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:50:15

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:19:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-07T18:30:13-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a03e3246-c42c-4f76-9e21-665d74fb2bbe'	System	08 Mar 2021 00:30:19
User entered 'No (N)'	System	08 Mar 2021 00:30:19

US3032187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:50:15

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:19:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (aadf87beb4d121f1)', Time: '2021-03-07T18:30:18-06:00', User OID: 'PatientReportedOutcome (US3032187)', ODM File OID: 'a03e3246-c42c-4f76-9e21-665d74fb2bbe' User entered '07 Mar 2021 18:30:18'	System	08 Mar 2021 00:30:19
	System	08 Mar 2021 00:30:19

US3032187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:41
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4)	24 Nov 2020 18:33:23

US3032187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:41
User entered '2 Nov 2020'	(b) (4) Russell Herstein (b) (4)	24 Nov 2020 18:33:23

US3032187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:41
User entered 'Contact Made (CONTACT MADE)'	Russell Herstein (b) (4)	24 Nov 2020 18:33:23

US3032187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:41
User entered empty.	Russell Herstein (b) (4)	24 Nov 2020 18:33:23

US3032187

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:41
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4)	24 Nov 2020 18:33:27

US3032187

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:55:21
User entered 'I'	System	24 Nov 2020 18:33:27

US3032187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	12 Mar 2021 19:45:43

US3032187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '8 Dec 2020'	Chelsie Nutsch (b) (4)	12 Mar 2021 19:45:43

US3032187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	12 Mar 2021 19:45:43

US3032187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	12 Mar 2021 19:45:43

US3032187

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 15:43:32

US3032187

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered 'I'	System	09 Jan 2021 15:43:32

US3032187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 15:43:44

US3032187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '4 Jan 2021'	Kelsey Kelley (b) (4)	09 Jan 2021 15:43:44

US3032187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4)	09 Jan 2021 15:43:44

US3032187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	09 Jan 2021 15:43:44

US3032187

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	09 Jan 2021 15:43:47

US3032187

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered 'I'	System	09 Jan 2021 15:43:47

US3032187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	26 Feb 2021 20:49:29

US3032187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered '2 Feb 2021'	Chelsie Nutsch (b) (4)	26 Feb 2021 20:49:29

US3032187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	26 Feb 2021 20:49:29

US3032187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered empty.	Chelsie Nutsch (b) (4)	26 Feb 2021 20:49:29

US3032187

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	26 Feb 2021 20:49:35

US3032187

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered 'I'	System	26 Feb 2021 20:49:35

US3032187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:16:31

US3032187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '11 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:16:31
	(b) (4)	

US3032187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Mar 2021 23:16:31

US3032187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered 'VISIT4'	System	11 Mar 2021 23:16:31

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered empty.	System	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered empty.	System	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered empty.	System	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered empty.	System	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered empty.	System	30 Mar 2021 21:25:01

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54

US3032187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54

US3032187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:17:09

US3032187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	Kelsey Kelley (b) (4)	11 Mar 2021 23:17:09

US3032187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:17:16

US3032187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '11 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:17:16
	(b) (4)	

US3032187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '13:07'	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:17:16

US3032187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered '11 Mar 2021 13:07'	System	11 Mar 2021 23:17:16

US3032187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:17:17

US3032187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:59:54
User entered 'I'	System	11 Mar 2021 23:17:17

US3032187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:55
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	07 Apr 2021 15:47:20

US3032187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:55
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '7 Apr 2021'	Chelsie Nutsch (b) (4)	07 Apr 2021 15:47:20

US3032187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:55
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	07 Apr 2021 15:47:20

US3032187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:55
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	07 Apr 2021 15:47:20

US3032187

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:55
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4)	07 Apr 2021 15:47:24

US3032187

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:44:55
User entered 'I'	System	07 Apr 2021 15:47:24

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:50:15

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:30
DataPoint Verified.		09 Mar 2021 18:22:28
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:41:07
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:41:07
	(b) (4)	
User entered '7 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	02 Feb 2021 20:41:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:29:35
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
User entered '10 Dec 2020'	Kelsey Kelley (b) (4)	10 Dec 2020 23:37:23
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:50:15

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:30
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:21:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:36:32
User closed query 'Per the source the time of contact was 12:45 please update' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 18:36:29
Query 'Per the source the time of contact was 12:45 please update' answered with 'updated' (Site from CRA).	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:13:50
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:13:34
User entered '12:45' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	22 Mar 2021 21:13:34
User opened query 'Per the source the time of contact was 12:45 please update' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 18:23:49
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 18:23:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:29:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	16 Dec 2020 20:09:42
User entered '14:40'	Kelsey Kelley (b) (4) (b) (4)	10 Dec 2020 23:37:23

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:50:15

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:30
User entered '7 Dec 2020 12:45'	System	22 Mar 2021 21:13:34
User entered '7 Dec 2020 14:40'	System	02 Feb 2021 20:41:07
User entered '10 Dec 2020 14:40'	System	10 Dec 2020 23:37:23

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:50:15

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:30
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:29:35
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Kelsey Kelley (b) (4)	10 Dec 2020 23:37:23

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:50:15

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:30
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:24:00
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:41:10
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:41:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:41:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:29:35
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Dec 2020 15:18:37
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	10 Dec 2020 23:37:23
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
New Information	Kelsey Kelley (b) (4)	02 Feb 2021 20:52:22
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:42:14
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:01
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '07 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:03
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:06
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:17
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:19
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:20
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Mild (Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:22
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:29
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:34
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:37
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:43
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Moderate (Moderate)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:45
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:48
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:50
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:53
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:51:56
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:51:58
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:00
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:02
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:42:14

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
New Information	Kelsey Kelley (b) (4)	02 Feb 2021 20:52:10
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:45:34
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '10 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '36.4' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:45:34

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
New Information	Kelsey Kelley (b) (4)	02 Feb 2021 20:52:03
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:46:21
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '11 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '93'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '96.7' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:46:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 12 (Day 12)'	Kelsey Kelley (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '12 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '98'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:54:21

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 13 (Day 13)'	(b) (4) Kelsey Kelley (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '13 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '100'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '97.9' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:06

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 14 (Day 14)'	(b) (4) Kelsey Kelley (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '14 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '96.5' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:55:40

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 15 (Day 15)'	(b) (4) Kelsey Kelley (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '15 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99.1' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:57:26

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 16 (Day 16)'	(b) (4) Kelsey Kelley (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '16 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '97.2' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:58:46

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 17 (Day 17)'	Kelsey Kelley (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '17 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '97.7' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 20:59:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 18 (Day 18)'	Kelsey Kelley (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '18 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '97'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '98.0' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 19 (Day 19)'	Kelsey Kelley (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '19 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99.0' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:00:44

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 20 (Day 20)'	(b) (4) Kelsey Kelley (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '20 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '98'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:01:36

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 21 (Day 21)'	Kelsey Kelley (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '21 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '98'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '98.5' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:00

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 22 (Day 22)'	(b) (4) Kelsey Kelley (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '22 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '98.4' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:02:37

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'Day 23 (Day 23)'	Kelsey Kelley (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '23 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '99'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered '%'	System	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered '98.6' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 22:48:40
DataPoint Verified.		2 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Feb 2021 21:03:41

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Day 1 (Day 1)'	(b) (4) Kelsey Kelley (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	10 Feb 2021 19:39:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 19:39:03
User entered '01 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	10 Feb 2021 19:39:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 19:38:55
User entered empty.	Kelsey Kelley (b) (4)	10 Feb 2021 19:38:55
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'I'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered empty.	System	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:38:55

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Day 2 (Day 2)'	(b) (4) Kelsey Kelley (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '02 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'I'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered empty.	System	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:12

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Day 3 (Day 3)'	(b) (4) Kelsey Kelley (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '03 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'I'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered empty.	System	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Day 4 (Day 4)'	(b) (4) Kelsey Kelley (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '04 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'I'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered empty.	System	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:49

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Day 5 (Day 5)'	(b) (4) Kelsey Kelley (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '05 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered empty.	System	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:40:58

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Day 6 (Day 6)'	Kelsey Kelley (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '06 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'I'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered empty.	System	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:19

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:55:44
User entered 'Day 8 (Day 8)'	Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '08 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered empty.	System	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:35

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Day 9 (Day 9)'	(b) (4) Kelsey Kelley (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '09 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'I'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
User entered empty.	System	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 14:50:15

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:40
DataPoint Verified.		12 Apr 2021 18:52:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Feb 2021 19:41:45

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
DataPoint Verified.		02 Feb 2021 20:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '10 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
DataPoint Verified.		02 Feb 2021 20:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
DataPoint Verified.		02 Feb 2021 20:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 05:26:48
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'added' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:25
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	11 Dec 2020 15:18:22
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
DataPoint Verified.		02 Feb 2021 20:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '10 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
DataPoint Verified.		02 Feb 2021 20:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
DataPoint Verified.		02 Feb 2021 20:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
DataPoint Verified.		02 Feb 2021 20:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
DataPoint Verified.		02 Feb 2021 20:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
DataPoint Verified.		02 Feb 2021 20:29:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:50:15

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:46
User entered 'I'	System	11 Dec 2020 15:18:22

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		12 Apr 2021 19:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	18 Dec 2020 14:42:11
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		12 Apr 2021 19:21:50
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	18 Dec 2020 14:42:11
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		12 Apr 2021 19:21:52
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	18 Dec 2020 14:42:11
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		12 Apr 2021 19:21:56
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:40:35
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
User entered '93' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	02 Feb 2021 20:53:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	18 Dec 2020 14:42:11
	(b) (4)	

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:50:15

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:53
DataPoint Verified.		02 Feb 2021 20:30:45
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Dec 2020 14:42:11

US3032187

Folder: Covid-19 Assessment 07 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:50:15

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:48:59
DataPoint Verified.		02 Feb 2021 20:30:52
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:59

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:50:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
User accepted default value 'Day 3 (Day 3)'	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:50:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.		09 Mar 2021 18:38:55
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.		09 Mar 2021 18:38:58
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '12 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:50:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
User accepted default value 'Day 5 (Day 5)'	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:50:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.		09 Mar 2021 18:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.		09 Mar 2021 18:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '14 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:50:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
User accepted default value 'Day 7 (Day 7)'	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:50:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.		09 Mar 2021 18:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	16 Dec 2020 14:40:02
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	14 Dec 2020 15:28:46
	(b) (4)	

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 16DEC2020 is reported in PPD central lab with 17DEC2020. Please review the PPD portal and confirm the correct date in response and amend EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 10:39:14
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 16DEC2020 is reported in PPD central lab with 17DEC2020. Please review the PPD portal and confirm the correct date in response and amend EDC or PPD portal as appropriate. Thank you.'	Samantha Wieseler (b) (4)	19 Jan 2021 23:40:42
answered with 'updated' (Site from DM).	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	19 Jan 2021 23:40:36
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 16DEC2020 is reported in PPD central lab with 17DEC2020. Please review the PPD portal and confirm the correct date in response and amend EDC or PPD portal as appropriate. Thank you.' (Site from DM).	Samantha Wieseler (b) (4)	19 Jan 2021 23:40:36
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 09:16:00
(Site from DM).		
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.'	Kelsey Kelley (b) (4)	28 Dec 2020 15:35:10
' answered with 'Correct as entered' (Site from DM).	(b) (4)	

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 07:35:51
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '16 Dec 2020' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 14:40:02
User entered empty.	Kelsey Kelley (b) (4)	14 Dec 2020 15:28:46
	(b) (4)	

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:50:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
User accepted default value 'Day 9 (Day 9)'	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:50:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.		09 Mar 2021 18:39:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is recorded under Illness Visit Day 9 in EDC, however 22DEC2020 is reported under Illness Visits Day 9 in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' (Site from DM).		20 Jan 2021 10:40:13
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is recorded under Illness Visit Day 9 in EDC, however 22DEC2020 is reported under Illness Visits Day 9 in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	19 Jan 2021 23:41:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is recorded under Illness Visit Day 9 in EDC, however 22DEC2020 is reported under Illness Visits Day 9 in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	30 Dec 2020 08:43:08
Signature has been broken.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	18 Dec 2020 21:54:55
User signature succeeded.	Kelsey Kelley (b) (4)	18 Dec 2020 21:54:55
User entered 'No (N)'	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	Kelsey Kelley (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.		09 Mar 2021 18:41:56
DataPoint Un-verified.		09 Mar 2021 18:41:45
DataPoint Verified.		09 Mar 2021 18:39:47
User closed query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 19DEC2020 is reported in PPD central lab with 22DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).		23 Feb 2021 11:53:40
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
Query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 19DEC2020 is reported in PPD central lab with 22DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4) Samantha Wieseler (b) (4)	28 Jan 2021 15:17:25
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 15:17:19
User opened query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 19DEC2020 is reported in PPD central lab with 22DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:19:38
Signature has been broken.	Samantha Wieseler (b) (4)	19 Jan 2021 23:41:08
User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4)	19 Jan 2021 23:41:08
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:54:15
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	18 Dec 2020 21:54:55
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	18 Dec 2020 21:54:55

PRODUCTION RELEASE (v12.003
EAB) (1725)

2611 of 3715

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:50:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
User accepted default value 'Day 14 (Day 14)'	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:50:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.		09 Mar 2021 19:16:41
DataPoint Un-verified.		09 Mar 2021 19:16:20
DataPoint Verified.		09 Mar 2021 18:39:47
User closed query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 24DEC2020 is reported in PPD central lab with 27DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).		23 Feb 2021 11:53:51
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
Query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 24DEC2020 is reported in PPD central lab with 27DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4) Samantha Wieseler (b) (4)	28 Jan 2021 15:18:11
User opened query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 24DEC2020 is reported in PPD central lab with 27DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:20:29
Signature has been broken.	Kelsey Kelley (b) (4)	28 Dec 2020 15:33:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	28 Dec 2020 15:33:38
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'No (N)'	Kelsey Kelley (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '27 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	28 Jan 2021 15:18:06
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 08:05:15
Query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'accession number is what was asked for and provided, please utilize to find info needed.' (Site from DM).	Samantha Wieseler (b) (4)	20 Jan 2021 22:34:17
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:40:36
User closed query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 23DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number to track the sample in PPD.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:40:36
Query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 23DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number to track the sample in PPD.' answered with 'Accession Number: 1F65858' (Site from DM).	Samantha Wieseler (b) (4)	19 Jan 2021 23:41:58
	(b) (4)	
User entered '24 Dec 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	19 Jan 2021 23:41:54
	(b) (4)	

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 23DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number to track the sample in PPD. ' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	07 Jan 2021 09:16:48
	(b) (4)	
	Kelsey Kelley (b) (4)	28 Dec 2020 15:33:38
	(b) (4)	
User entered '23 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	28 Dec 2020 15:33:38
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	14 Dec 2020 15:28:46
	(b) (4)	

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:50:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F636371608 is reported with 03JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).		19 Feb 2021 07:01:13
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F636371608 is reported with 03JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' answered with 'updated but will update Preclarus as well as date is not right' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	10 Feb 2021 16:24:12
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F636371608 is reported with 03JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 16:23:30
User accepted default value 'Day 21 (Day 21)'	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:50:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.	(b) (4)	09 Mar 2021 18:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	10 Feb 2021 16:23:54
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	10 Feb 2021 16:23:54
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	14 Dec 2020 15:28:46
	(b) (4)	

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.	(b) (4)	09 Mar 2021 18:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	10 Feb 2021 16:23:54
	(b) (4)	
User entered '31 Dec 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	10 Feb 2021 16:23:54
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	14 Dec 2020 15:28:46
	(b) (4)	

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:50:15

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
User closed query 'Per GCL LAB reconciliation: Saliva requery : PPD reports Day 28 sample with Accession # 1F634439404 is reported with 12JAN2021 Date of Collection however in EDC for Day 28 is marked as "No". Please review the Accession # in Preclarus to confirm the correct date and amend EDC Thank you.' (Site from DM).		01 Mar 2021 04:49:50
Query 'Per GCL LAB reconciliation: Saliva requery : Samantha Wieseler PPD reports Day 28 sample with Accession # 1F634439404 is reported with 12JAN2021 Date of Collection however in EDC for Day 28 is marked as "No". Please review the Accession # in Preclarus to confirm the correct date and amend EDC Thank you.'	(b) (4) (b) (4)	25 Feb 2021 17:23:54
answered with 'Day 28 saliva was for Convalescent Day 28' (Site from DM).		
User opened query 'Per GCL LAB reconciliation: Saliva requery : PPD reports Day 28 sample with Accession # 1F634439404 is reported with 12JAN2021 Date of Collection however in EDC for Day 28 is marked as "No". Please review the Accession # in Preclarus to confirm the correct date and amend EDC Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 19:33:43
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F634439404 is reported with 12JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).		23 Feb 2021 11:54:05
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F634439404 is reported with 12JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' answered with 'sample was collected under Convalescent Day 28' (Site from DM).	Samantha Wieseler (b) (4)	10 Feb 2021 16:24:48

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:50:15

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 28 sample with Accession # 1F634439404 is reported with 12JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 16:24:17
User accepted default value 'Day 28 (Day 28)'	Kelsey Kelley (b) (4) (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:50:15

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.		08 Apr 2021 17:50:19
User closed query 'Per GCL lab and this sample was collected please update.' (Site from CRA).		08 Apr 2021 17:50:17
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
Query 'Per GCL lab and this sample was collected please update.' answered with 'Updated' (Site from CRA).	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:28:10
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:27:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:27:57
User opened query 'Per GCL lab and this sample was collected please update.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 19:26:44
DataPoint Un-verified.		09 Mar 2021 19:17:57
DataPoint Verified.		09 Mar 2021 18:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	14 Dec 2020 15:28:46

US3032187

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:33
DataPoint Verified.	(b) (4)	08 Apr 2021 17:50:21
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	11 Mar 2021 23:27:57
	(b) (4)	
User entered '12 Jan 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Mar 2021 23:27:57
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 20:20:32
DataPoint Verified.	(b) (4)	09 Mar 2021 18:39:47
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	14 Dec 2020 15:28:46
	(b) (4)	

US3032187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:51
DataPoint Verified.		02 Feb 2021 20:31:05
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Dec 2020 23:59:47

US3032187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:51
DataPoint Verified.		02 Feb 2021 20:31:05
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '10 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Dec 2020 23:59:47

US3032187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:51
DataPoint Verified.		02 Feb 2021 20:31:05
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	10 Dec 2020 23:59:47

US3032187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:51
User entered 'SICKD1'	System	10 Dec 2020 23:59:47

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '10 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '14:40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
User entered '10 Dec 2020 14:40'	System	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '176.5' cm	(b) (4) Kelsey Kelley (b) (4)	11 Dec 2020 00:03:10
DataPoint set to visible.	(b) (4) System	10 Dec 2020 23:59:47

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '98.0' kg	(b) (4) Kelsey Kelley (b) (4)	11 Dec 2020 00:03:10
DataPoint set to visible.	(b) (4) System	10 Dec 2020 23:59:47

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '36.4' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '81'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
User entered 'bpm'	System	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
User entered 'breaths/min'	System	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '108'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
User entered 'mmHg'	System	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
DataPoint Verified.		02 Feb 2021 20:31:40
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '70'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55
User entered 'mmHg'	System	11 Dec 2020 00:03:10

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55

US3032187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:55

US3032187

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:59
DataPoint Verified.		02 Feb 2021 20:31:52
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:17

US3032187

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:59
DataPoint Verified.		02 Feb 2021 20:31:52
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '10 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:17

US3032187

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:50:15

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:03
DataPoint Verified.		02 Feb 2021 20:32:01
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:32

US3032187

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:03
DataPoint Verified.		02 Feb 2021 20:32:01
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 04:24:51
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'samples have been shipped' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Dec 2020 19:48:41
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 11:10:39
User entered '10 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 00:03:32

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:10
DataPoint Verified.		09 Mar 2021 18:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
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	12 Jan 2021 21:45:16
User entered 'Yes (Y)' reason for change: Data Entry Error	System	12 Jan 2021 21:45:16
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	12 Jan 2021 21:45:16
User entered empty.	(b) (4)	
	System	12 Jan 2021 21:45:05
	Kelsey Kelley (b) (4)	12 Jan 2021 21:45:05
	(b) (4)	

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:10
DataPoint Verified.		09 Mar 2021 18:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '12 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:05

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:10
DataPoint Verified.		09 Mar 2021 18:27:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:05

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:10
User entered 'SICKD28'	System	12 Jan 2021 21:45:16
User entered empty.	System	12 Jan 2021 21:45:05

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '12 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '15:10'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
User entered '12 Jan 2021 15:10'	System	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '175.2' cm	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 21:45:59
DataPoint set to visible.	(b) (4) System	12 Jan 2021 21:45:16

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '95.5' kg	(b) (4) Kelsey Kelley (b) (4)	12 Jan 2021 21:45:59
DataPoint set to visible.	(b) (4) System	12 Jan 2021 21:45:16

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '37.1' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '81'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
User entered 'bpm'	System	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
User entered 'breaths/min'	System	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '116'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
User entered 'mmHg'	System	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
DataPoint Verified.		09 Mar 2021 18:28:47
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '67'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19
User entered 'mmHg'	System	12 Jan 2021 21:45:59

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:19

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:23
DataPoint Verified.		09 Mar 2021 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:46:04

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:23
DataPoint Verified.		09 Mar 2021 18:28:58
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '12 Jan 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:46:04

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:50:15

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:27
DataPoint Verified.		09 Mar 2021 18:34:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	12 Jan 2021 21:46:16

US3032187

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:50:15

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:27
DataPoint Verified.		09 Mar 2021 18:34:51
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).		10 Feb 2021 08:53:07
Query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'will update accordingly' (Site from DM).	Samantha Wieseler (b) (4)	01 Feb 2021 22:27:23
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:12:53
User signature succeeded.	Keith Vrbicky (b) (4)	18 Jan 2021 19:28:44
User entered '12 Jan 2021'	Kelsey Kelley (b) (4)	12 Jan 2021 21:46:16

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:12

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22DEC2020 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).		11 Feb 2021 05:58:56
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22DEC2020 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'will update when available' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	10 Feb 2021 16:28:05
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22DEC2020 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:37:39
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	30 Jan 2021 16:50:28
User entered '20 Jan 2021'	Kelsey Kelley (b) (4) (b) (4)	20 Jan 2021 19:02:12

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[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 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	20 Jan 2021 19:02:12

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 19:02:12

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '20 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:37
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:15:58

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:15:58

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '20 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:37
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered '1'	System	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:15

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'I'	System	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered empty.	System	20 Jan 2021 19:09:21
DataPoint set to visible.	System	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered empty.	System	20 Jan 2021 19:09:21
DataPoint set to visible.	System	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '20 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '11:40'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered '20 Jan 2021 11:40'	System	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '71'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'bpm'	System	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '17'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'breaths/min'	System	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '112'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mmHg'	System	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '74'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mmHg'	System	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:21

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered empty.	System	20 Jan 2021 19:09:21
DataPoint set to visible.	System	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '20 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '12:25'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered '20 Jan 2021 12:25'	System	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'bpm'	System	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'breaths/min'	System	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '121'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mmHg'	System	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '81'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mmHg'	System	20 Jan 2021 19:09:44

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:03:16

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '20 Jan 2021'	Kelsey Kelley (b) (4)	20 Jan 2021 19:03:16

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:05:13

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:05:13

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

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 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered empty.	Kelsey Kelley (b) (4)	20 Jan 2021 19:05:13

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mRNA-1273'	System	20 Jan 2021 19:05:13
DataPoint set to visible.	System	20 Jan 2021 19:02:37

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '20 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:05:13
	(b) (4)	

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '11:52'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:05:13

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered '20 Jan 2021 11:52'	System	20 Jan 2021 19:05:13

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Right Arm (RIGHT ARM)'	Kelsey Kelley (b) (4)	20 Jan 2021 19:05:13

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'ONCE'	System	20 Jan 2021 19:05:13

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 19:05:13

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:53

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User closed query 'Per GCL Lab Recon:OL Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this "OL-D1" sample, as in PPD GCL, it is recorded as collected on "22 DEC 2020", however here in EDC, it is recorded as collected on "20 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM).		31 Mar 2021 10:35:24
Query 'Per GCL Lab Recon:OL Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this "OL-D1" sample, as in PPD GCL, it is recorded as collected on "22 DEC 2020", however here in EDC, it is recorded as collected on "20 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' answered with 'was collected 20Jan2021' (Site from DM).	Samantha Wieseler (b) (4)	22 Mar 2021 18:21:54
User opened query 'Per GCL Lab Recon:OL Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this "OL-D1" sample, as in PPD GCL, it is recorded as collected on "22 DEC 2020", however here in EDC, it is recorded as collected on "20 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 10:16:31
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '20 Jan 2021'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:53

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '11:12'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:02:53

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered '20 Jan 2021 11:12'	System	20 Jan 2021 19:02:53

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:03:01

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:50:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 20JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 06:01:54
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 20JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'will update when updates available' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	10 Feb 2021 16:25:38
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 20JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:55:23
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 20JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:55:10
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 20JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:51:47

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:50:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22DEC2020 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please review and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:49:22
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22DEC2020 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please review and update the details under appropriate visit. Thank you.' answered with 'sample was collected on 20Jan2021' (Site from DM).	Samantha Wieseler (b) (4)	01 Feb 2021 22:27:51
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 22DEC2020 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please review and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:19:16
User entered '20 Jan 2021'	Kelsey Kelley (b) (4)	20 Jan 2021 19:03:01

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:50:15

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '11:14'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:03:01

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:50:15

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered '20 Jan 2021 11:14'	System	20 Jan 2021 19:03:01

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	20 Jan 2021 19:03:04

US3032187

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'I'	System	20 Jan 2021 19:03:04

US3032187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Feb 2021 22:21:41

US3032187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '27 Jan 2021'	Kelsey Kelley (b) (4)	19 Feb 2021 22:21:41

US3032187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Contact Made (CONTACT MADE)'	Kelsey Kelley (b) (4)	19 Feb 2021 22:21:41

US3032187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 22:21:41

US3032187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	19 Feb 2021 22:21:47

US3032187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User entered 'I'	System	19 Feb 2021 22:21:47

US3032187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User entered '1'	System	19 Feb 2021 22:21:47
DataPoint set to visible.	System	19 Feb 2021 22:21:47

US3032187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:21:55

US3032187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '19 Feb 2021'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:21:55
	(b) (4)	

US3032187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[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 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	19 Feb 2021 22:21:55

US3032187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'OLD29'	System	19 Feb 2021 22:21:55

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '19 Feb 2021'	Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '08:05'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered '19 Feb 2021 08:05'	System	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05
	(b) (4)	

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05
	(b) (4)	

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '99'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'bpm'	System	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '15'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'breaths/min'	System	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '119'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05
	(b) (4)	

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mmHg'	System	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '78'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mmHg'	System	19 Feb 2021 22:23:05

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '19 Feb 2021'	Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '09:28'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered '19 Feb 2021 09:28'	System	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '36.9' C	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30
	(b) (4)	

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '85'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'bpm'	System	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'breaths/min'	System	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '110'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mmHg'	System	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '73'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mmHg'	System	19 Feb 2021 22:24:30

US3032187

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:22:36

US3032187

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '19 Feb 2021'	Kelsey Kelley (b) (4)	19 Feb 2021 22:22:36

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:53

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:53

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

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 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:53
	(b) (4)	

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'mRNA-1273'	System	19 Feb 2021 22:23:53
DataPoint set to visible.	System	19 Feb 2021 22:21:47

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '19 Feb 2021'	Kelsey Kelley (b) (4)	19 Feb 2021 22:23:53

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '08:57'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:53

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered '19 Feb 2021 08:57'	System	19 Feb 2021 22:23:53

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Right Arm (RIGHT ARM)'	Kelsey Kelley (b) (4)	19 Feb 2021 22:23:53

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'ONCE'	System	19 Feb 2021 22:23:53

US3032187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 22:23:53

US3032187

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	19 Feb 2021 22:23:57

US3032187

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:25
User entered 'I'	System	19 Feb 2021 22:23:57

US3032187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	26 Feb 2021 19:28:04

US3032187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered '26 Feb 2021'	Chelsie Nutsch (b) (4)	26 Feb 2021 19:28:04

US3032187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	26 Feb 2021 19:28:04

US3032187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered empty.	Chelsie Nutsch (b) (4)	26 Feb 2021 19:28:04

US3032187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User signature succeeded.	Keith Vrbicky (b) (4)	04 Mar 2021 16:03:02
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	26 Feb 2021 19:28:09

US3032187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:26
User entered 'I'	System	26 Feb 2021 19:28:09

US3032187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	02 Apr 2021 18:50:59
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered '2 Apr 2021'	Kelsey Kelley (b) (4)	02 Apr 2021 18:50:59
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered 'Clinic (Clinic)'	Kelsey Kelley (b) (4)	02 Apr 2021 18:50:59
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	02 Apr 2021 18:50:59

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered '2 Apr 2021'	Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered '13:16'	Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Apr 2021 13:16'	System	02 Apr 2021 18:51:57

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered '36.9' C	Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered '84'	Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Apr 2021 18:51:57

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered '16'	Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Apr 2021 18:51:57

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '133'	(b) (4) Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 18:51:57

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '83' reason for change: Data Entry Error	System	02 Apr 2021 18:52:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Kelsey Kelley (b) (4)	02 Apr 2021 18:52:05
User entered '83.' (non-conformant).	(b) (4)	
	System	02 Apr 2021 18:51:57
	Kelsey Kelley (b) (4)	02 Apr 2021 18:51:57
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Apr 2021 18:52:05
User entered empty.	System	02 Apr 2021 18:51:57

US3032187

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered 'No (N)'	Kelsey Kelley (b) (4)	02 Apr 2021 18:52:12
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	02 Apr 2021 18:52:12
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	02 Apr 2021 18:52:24
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered '2 Apr 2021'	Kelsey Kelley (b) (4)	02 Apr 2021 18:52:24
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered '13:16'	Kelsey Kelley (b) (4)	02 Apr 2021 18:52:24
	(b) (4)	

US3032187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Apr 2021 13:16'	System	02 Apr 2021 18:52:24

US3032187

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:50:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:01
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE and JOINT ACHES (start date: Day 3; end date: Day 16) persist beyond Day 7 . Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).		09 Apr 2021 12:09:47
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 4; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).		09 Apr 2021 12:09:42
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE and JOINT ACHES (start date: Day 3; end date: Day 16) persist beyond Day 7 . Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:50:41
' answered with 'Updated AE log' (Site from DM). Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 4; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.	Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:50:27
' answered with 'Updated AE log.' (Site from DM). User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE and JOINT ACHES (start date: Day 3; end date: Day 16) persist beyond Day 7 . Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:45:42

US3032187

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:50:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 4; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:45:38
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 222 (21MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:07:40
User closed query 'Per DM CLR: Per diary record, symptom of Muscle Aches all over the body persist beyond 7 days (start date: 10 Sep 2020; end date: 23 Sep 2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:07:37
Query 'Per DM CLR: Per diary record, symptom of Muscle Aches all over the body persist beyond 7 days (start date: 10 Sep 2020; end date: 23 Sep 2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol and update AE eCRF as appropriate. Else, provide clarification.' answered with 'was not AE reporting criteria' (Site from DM).	Samantha Wieseler (b) (4)	30 Mar 2021 19:21:09
User opened query 'Per DM CLR: Per diary record, symptom of Muscle Aches all over the body persist beyond 7 days (start date: 10 Sep 2020; end date: 23 Sep 2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 03:41:12

US3032187

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:50:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Safety Follow Up Diary Day 222 (21MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'no ae needed' (Site from DM).	Samantha Wieseler (b) (4)	29 Mar 2021 14:13:59
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 222 (21MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:08:56
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:18:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	07 Dec 2020 21:53:27
User entered 'No (N)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	01 Dec 2020 20:16:37
Signature has been broken.	Linden DeBoer (b) (4)	01 Dec 2020 20:14:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	01 Dec 2020 20:14:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	Kelsey Kelley (b) (4)	11 Aug 2020 20:47:42

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 12:16:17
DataPoint Verified.		09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered	(b) (4)	
'USA-US032-2020-mRNA-1273-P301000021'	System	08 Dec 2020 16:44:56
User entered 'New'	(b) (4), (b) (6)	08 Dec 2020 16:44:56

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 21:59:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 21:59:46
Data point term sent to Coder	System	07 Dec 2020 21:58:42
User entered 'Covid 19'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User closed query 'PV Query: Start date is reported as 30Nov2020. Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. Please leave query open until information is available.' (Site from Safety). Query 'PV Query: Start date is reported as 30Nov2020. Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. Please leave query open until information is available.' answered with 'will update the COVID-19 assessment symptom log' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:30:22
User opened query 'PV Query: Start date is reported as 30Nov2020. Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. Please leave query open until information is available.' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:22:50
User closed query 'PV Query: Start date is reported as 30Nov2020. Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. ' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Start date is reported as 30Nov2020. Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:29:38
User closed query 'PV Query: Start date is reported as 30Nov2020. Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. ' (Site from Safety).		19 Jan 2021 13:14:32
Query 'PV Query: Start date is reported as 30Nov2020. Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. ' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	15 Jan 2021 01:10:02
User opened query 'PV Query: Start date is reported as 30Nov2020. Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. ' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 10:59:28
User entered '30 Nov 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	28 Dec 2020 16:58:56
Signature has been broken.	Kelsey Kelley (b) (4)	11 Dec 2020 15:15:54
User entered '1 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Dec 2020 15:15:54
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58

PRODUCTION RELEASE (v12.003
EAB) (1725)

2853 of 3715

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Dec 2020'	Linden DeBoer (b) (4) (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered empty.	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
Signature has been broken.	System	11 Dec 2020 15:16:18
	Kelsey Kelley (b) (4)	11 Dec 2020 15:16:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	11 Dec 2020 15:16:18
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User signature succeeded.	System	11 Dec 2020 15:15:54
	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Yes (Y)'	(b) (4)	
	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User closed query 'PV Query: The event of COVID 19 was considered resolved on 09 Dec 2020. Per the Covid-19 severity log, the subject experienced an oxygen saturation of 93% on 11 Dec 2020. Please confirm the resolution date or clarify.' (Site from Safety).		22 Feb 2021 15:28:54
Query 'PV Query: The event of COVID 19 was considered resolved on 09 Dec 2020. Per the Covid-19 severity log, the subject experienced an oxygen saturation of 93% on 11 Dec 2020. Please confirm the resolution date or clarify.' answered with 'The resolution date stands as entered. The subject did report an o2 saturation of 93% on 11Dec2020. His PCP was aware of low oxygen reading and stated this is part of his post-covid recovery period. ' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 16:07:45
User opened query 'PV Query: The event of COVID 19 was considered resolved on 09 Dec 2020. Per the Covid-19 severity log, the subject experienced an oxygen saturation of 93% on 11 Dec 2020. Please confirm the resolution date or clarify.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 18:33:29
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:55:44
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 15:17:28
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	11 Dec 2020 15:17:28
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 15:15:54
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:15:54
User entered '9 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	11 Dec 2020 15:15:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

2858 of 3715

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered empty.	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered empty.	(b) (4)	07 Dec 2020 21:58:11
	Linden DeBoer (b) (4)	
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: The SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab was positive on 10 Dec 2020. Please confirm the event end date (for when symptoms resolved). ' canceled (Site from Safety). User opened query 'PV Query: The SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab was positive on 10 Dec 2020. Please confirm the event end date (for when symptoms resolved). ' (Site from Safety). User entered empty.	(b) (4), (b) (6)	12 Jan 2021 10:51:31
		07 Jan 2021 14:07:27
	System	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '0'	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '0'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User closed query 'Per CDM: Please update the Hospital Discharge Date and Admitted to ICU once the data is available.' (Site from DM).		29 Dec 2020 06:39:17
Query 'Per CDM: Please update the Hospital Discharge Date and Admitted to ICU once the data is available.' answered with 'Added discharge date.' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:40:59
User opened query 'Per CDM: Please update the Hospital Discharge Date and Admitted to ICU once the data is available.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:30:16
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		11 Dec 2020 09:29:22
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:47:58
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'no medical records yet. will update as information is available' (Site from System).	Linden DeBoer (b) (4) (b) (4)	07 Dec 2020 22:00:22
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	07 Dec 2020 21:58:11
User entered 'I'	Linden DeBoer (b) (4) (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:00:27
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Chelsie Nutsch (b) (4)	12 Mar 2021 19:37:09
Signature has been broken.	(b) (4)	
	Chelsie Nutsch (b) (4)	12 Mar 2021 19:21:08
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Chelsie Nutsch (b) (4)	12 Mar 2021 19:21:08
	(b) (4), (b) (6)	09 Mar 2021 20:25:15
User closed query 'PV Query: The event COVID 19 has a hospital admission date of 03 Dec 2020, and the event diabetes mellitus type 2 has an admission date of 04 Dec 2020. Please confirm which hospital admission date is correct, 03Dec or 04Dec, and update event accordingly.' (Site from Safety).		22 Jan 2021 16:30:30
Query 'PV Query: The event COVID 19 has a hospital admission date of 03 Dec 2020, and the event diabetes mellitus type 2 has an admission date of 04 Dec 2020. Please confirm which hospital admission date is correct, 03Dec or 04Dec, and update event accordingly.' answered with 'both admission dates are correct. Subject was hospitalized on 03Dec2020 for Covid-19 and while in the hospital was diagnosed with diabetes mellitus. Diabetes was officially diagnosed on 04Dec2020' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:24:11
	(b) (4)	
User opened query 'PV Query: The event COVID 19 has a hospital admission date of 03 Dec 2020, and the event diabetes mellitus type 2 has an admission date of 04 Dec 2020. Please confirm which hospital admission date is correct, 03Dec or 04Dec, and update event accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:29:18
User closed query 'PV Query: The event COVID 19 has a hospitalization date of 03 Dec 2020, and the event diabetes mellitus type 2 has a hospitalization date of 04 Dec 2020. Please confirm hospitalization dates or update as applicable.' (Site from Safety).		19 Jan 2021 13:14:28

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: The event COVID 19 has a hospitalization date of 03 Dec 2020, and the event diabetes mellitus type 2 has a hospitalization date of 04 Dec 2020. Please confirm hospitalization dates or update as applicable.' answered with 'hospitalization dates are correct' (Site from Safety).	Samantha Wieseler (b) (4)	15 Jan 2021 01:10:18
User opened query 'PV Query: The event COVID 19 has a hospitalization date of 03 Dec 2020, and the event diabetes mellitus type 2 has a hospitalization date of 04 Dec 2020. Please confirm hospitalization dates or update as applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 10:57:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '3 Dec 2020'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:28:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records sent' (Site from Safety).	Samantha Wieseler (b) (4) (b) (4)	11 Feb 2021 20:07:58
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 21:17:26
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:40:50
User entered '07 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:40:50
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:47:58
User entered empty.	Linden DeBoer (b) (4) (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:37
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).		11 Dec 2020 09:30:19
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'information is unknown at this time' (Site from System).	(b) (4)	
	Linden DeBoer (b) (4)	07 Dec 2020 22:00:35
	(b) (4)	
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	07 Dec 2020 21:58:11
User entered 'Unknown (UNK)'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:40
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered empty.	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '0'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:43
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '0'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:45
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '0'	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:50
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Signature has been broken.	Kelsey Kelley (b) (4)	28 Dec 2020 16:40:32
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4)	28 Dec 2020 16:40:32
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Not Applicable (NOT APPLICABLE)'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:52
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Signature has been broken.	Kelsey Kelley (b) (4)	28 Dec 2020 16:40:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	28 Dec 2020 16:40:32
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Not Applicable (NOT APPLICABLE)'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:55
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:25:57
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	11 Dec 2020 15:16:18
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Dec 2020 15:16:18
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Dec 2020 21:59:46
User entered '1' reason for change: Data Entry Error	Linden DeBoer (b) (4)	07 Dec 2020 21:59:46
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Dec 2020 21:58:11
User entered '0'	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:26:00
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Signature has been broken.	(b) (4)	11 Dec 2020 15:16:18
	Kelsey Kelley (b) (4)	11 Dec 2020 15:16:18
User entered '1' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 15:16:18
	Kelsey Kelley (b) (4)	11 Dec 2020 15:16:18
User signature succeeded.	(b) (4)	08 Dec 2020 19:47:58
	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '0'	(b) (4)	07 Dec 2020 21:58:11
	Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:26:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '0'	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:26:24
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	11 Dec 2020 15:17:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) Kelsey Kelley (b) (4)	11 Dec 2020 15:17:28
Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:26:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered empty.	(b) (4) Linden DeBoer (b) (4)	07 Dec 2020 21:58:11
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User closed query 'Per DM CLR: Narrative = ADMISSION DATE 04 DEC. However, recorded admission date is 03DEC2020. Review and reconcile data as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 01:17:53
User closed query 'Per DM CLR: Narrative = HIS HGBA1C WAS 12.5, ADMITTING BLOOD GLUCOSE 466. However, this is not recorded in the ConProc eCRF (i.e., Blood Work-up). Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).		16 Mar 2021 01:17:48
User closed query 'Per DM CLR: Narrative = ON 03 DEC-04 DEC HE BEGAN TO EXHIBIT SYMPTOMS OF ENCEPHALOPATHY INCLUDING LETHARGY AND CONFUSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		16 Mar 2021 01:17:09
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:37:09

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED TO REPORT SAE. SUBJECT WAS STILL IN HOSPITAL AT THE TIME OF THE CALL. SUBJECT WILL CALL AGAIN IN THE MORNING IF DISCHARGED AND SIGN A MEDICAL RELEASE FORM. UPDATE 28 DEC: MEDICAL RECORDS REVIEWED. IN SUMMARY: SUBJECT DIAGNOSED WITH COVID ON 30 NOV 2020. ON 03 DEC-04 DEC HE BEGAN TO EXHIBIT SYMPTOMS OF ENCEPHALOPATHY INCLUDING LETHARGY AND CONFUSION. HE WAS TAKEN TO THE ER ON 03 DEC AND ADMITTED. HE UTILIZED IV DEXAMETHASONE AND REMDESIVIR AND AT THIS TIME DIAGNOSED WITH DIABETES MELLITUS TYPE 2. HIS HGBA1C WAS 12.5, ADMITTING BLOOD GLUCOSE 466. HE WAS STARTED ON BOTH LONG AND SHORT ACTING INSULIN, LISINAPRIL, AND SIMVASTATIN. ON DISCHARGE HE CONTINUED ORAL DEXAMETHASONE. ADMISSION DATE 04 DEC, DISCHARGE 07 DEC. HE WAS ON OXYGEN VIA NASAL CANNULA <24 HOURS. UPDATE 10FEB: SUBJECT CALLED TO CLARIFY INFORMATION. STATES INITIAL COVID TEST PERFORMED AT PCP OFFICE ON 30NOV2020 DUE TO SYMPTOMS OF SHORTNESS OF BREATH, COUGH, BODY ACHES, MYALGIA, ARTHRALGIA, AND HEADACHE.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:37:09
Query 'Per DM CLR: Narrative = HIS HGBA1C WAS 12.5, ADMITTING BLOOD GLUCOSE 466. However, this is not recorded in the ConProc eCRF (i.e., Blood Work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'done. thank you' (Site from DM).	Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:27:03

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = ON 03 DEC-04 DEC HE BEGAN TO EXHIBIT SYMPTOMS OF ENCEPHALOPATHY INCLUDING LETHARGY AND CONFUSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Created a separate AE. thank you' (Site from DM).	Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:26:48
Query 'Per DM CLR: Narrative = ADMISSION DATE 04 DEC. However, recorded admission date is 03DEC2020. Review and reconcile data as appropriate. Otherwise, clarify. ' answered with 'data updated. admission date is 04Dec' (Site from DM).	Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:21:24
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 20:31:08
DataPoint Verified.		09 Mar 2021 20:26:33
User opened query 'Per DM CLR: Narrative = ADMISSION DATE 04 DEC. However, recorded admission date is 03DEC2020. Review and reconcile data as appropriate. Otherwise, clarify. ' (Site from DM).		28 Feb 2021 02:01:33
User opened query 'Per DM CLR: Narrative = HIS HGBA1C WAS 12.5, ADMITTING BLOOD GLUCOSE 466. However, this is not recorded in the ConProc eCRF (i.e., Blood Work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		28 Feb 2021 02:01:19
User opened query 'Per DM CLR: Narrative = ON 03 DEC-04 DEC HE BEGAN TO EXHIBIT SYMPTOMS OF ENCEPHALOPATHY INCLUDING LETHARGY AND CONFUSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		28 Feb 2021 02:00:52

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for reporting COVID-19 testing details performed on 30 Nov 2020 have been requested from the PCP. Please provide this information once available. Please include why the subject was tested (i.e. exposure, symptoms, etc.).Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 15:29:00
Query 'PV Query: Thank you for reporting COVID-19 testing details performed on 30 Nov 2020 have been requested from the PCP. Please provide this information once available. Please include why the subject was tested (i.e. exposure, symptoms, etc.).Please leave query open until information is available.' answered with 'see narrative update on 10Feb for initial symptoms' (Site from Safety).	Chelsie Nutsch (b) (4)	19 Feb 2021 16:03:10
User opened query 'PV Query: Thank you for reporting COVID-19 testing details performed on 30 Nov 2020 have been requested from the PCP. Please provide this information once available. Please include why the subject was tested (i.e. exposure, symptoms, etc.).Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 18:34:18
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User closed query 'PV Query: The subject tested positive for COVID-19 on 30Nov2020. Please confirm where this test was performed and why the subject was tested (i.e. exposure, symptoms, etc.).Please leave query open until information is available' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:36:29
User closed query 'PV Query: Please complete the Covid-19 symptoms log starting from 30Nov2020 (when subject tested positive). Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 14:36:24

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please complete the Covid-19 symptoms log starting from 30Nov2020 (when subject tested positive). Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. Please leave query open until information is available.' answered with 'data updated' (Site from Safety).	Chelsie Nutsch (b) (4)	10 Feb 2021 16:51:22
User entered 'SUBJECT CALLED TO REPORT SAE. SUBJECT WAS STILL IN HOSPITAL AT THE TIME OF THE CALL. SUBJECT WILL CALL AGAIN IN THE MORNING IF DISCHARGED AND SIGN A MEDICAL RELEASE FORM. UPDATE 28 DEC: MEDICAL RECORDS REVIEWED. IN SUMMARY: SUBJECT DIAGNOSED WITH COVID ON 30 NOV 2020. ON 03 DEC-04 DEC HE BEGAN TO EXHIBIT SYMPTOMS OF ENCEPHALOPATHY INCLUDING LETHARGY AND CONFUSION. HE WAS TAKEN TO THE ER ON 04 DEC AND ADMITTED. HE UTILIZED IV DEXAMETHASONE AND REMDESIVIR AND AT THIS TIME DIAGNOSED WITH DIABETES MELLITUS TYPE 2. HIS HGBA1C WAS 12.5, ADMITTING BLOOD GLUCOSE 466. HE WAS STARTED ON BOTH LONG AND SHORT ACTING INSULIN, LISINOPRIL, AND SIMVASTATIN. ON DISCHARGE HE CONTINUED ORAL DEXAMETHASONE. ADMISSION DATE 04 DEC, DISCHARGE 07 DEC. HE WAS ON OXYGEN VIA NASAL CANNULA <24 HOURS. Update 10Feb: Subject called to clarify information. states initial covid test performed at PCP office on 30Nov2020 due to symptoms of shortness of breath, cough, body aches, myalgia, arthralgia, and headache.' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	10 Feb 2021 16:50:28

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The subject tested positive for COVID-19 on 30Nov2020. Please confirm where this test was performed and why the subject was tested (i.e. exposure, symptoms, etc.).Please leave query open until information is available' answered with 'test performed at PCP office. Records requested. ' (Site from Safety).	Chelsie Nutsch (b) (4)	10 Feb 2021 16:48:17
User opened query 'PV Query: The subject tested positive for COVID-19 on 30Nov2020. Please confirm where this test was performed and why the subject was tested (i.e. exposure, symptoms, etc.).Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 21:19:45
User opened query 'PV Query: Please complete the Covid-19 symptoms log starting from 30Nov2020 (when subject tested positive). Please provide signs and symptoms of COVID 19 and update the COVID-19 assessments Symptom log appropriately. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 21:17:56
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until available. ' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:30:41
User closed query 'PV Query: The subject tested positive for COVID-19 on 30Nov2020. Please confirm where this test was performed and why the subject was tested (i.e. exposure, symptoms, etc.).Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:30:36
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until available. ' answered with 'Records have been requested and have not been received ' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:24:54

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The subject tested positive for COVID-19 on 30Nov2020. Please confirm where this test was performed and why the subject was tested (i.e. exposure, symptoms, etc.).Please leave query open until information is available.' answered with 'Test was performed at PCP. will update symptoms. ' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:24:39
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until available. ' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:34:16
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:34:16
User opened query 'PV Query: The subject tested positive for COVID-19 on 30Nov2020. Please confirm where this test was performed and why the subject was tested (i.e. exposure, symptoms, etc.).Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:30:22
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'we are attempting to obtain medical discharge from hospital. ' (Site from Safety).	Samantha Wieseler (b) (4)	19 Jan 2021 23:37:28
User closed query 'PV Query: The subject tested positive for COVID-19 on 30Nov2020. Please confirm where this test was performed and why the subject was tested (i.e. exposure, symptoms, etc.).' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 13:14:25

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The subject tested positive for COVID-19 on 30Nov2020. Please confirm where this test was performed and why the subject was tested (i.e. exposure, symptoms, etc.).' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	15 Jan 2021 01:11:22
User opened query 'PV Query: The subject tested positive for COVID-19 on 30Nov2020. Please confirm where this test was performed and why the subject was tested (i.e. exposure, symptoms, etc.).' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 11:01:52
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 10:57:44
User closed query 'PV Query: Please provide signs and symptoms of COVID 19 (and when they started). If unknown, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 14:50:15
User closed query 'PV Query: The event COVID 19 has a hospitalization date of 03 Dec 2020, and the event diabetes mellitus type 2 has a hospitalization date of 04 Dec 2020. Please confirm hospitalization dates or update as applicable. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 14:50:10
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 14:50:06
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 14:49:05
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 14:47:30

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide signs and symptoms of COVID 19 (and when they started). If unknown, please state so. ' answered with 'will update accordingly' (Site from Safety).	Samantha Wieseler (b) (4)	(b) (4) 09 Jan 2021 16:50:28
Query 'PV Query: The event COVID 19 has a hospitalization date of 03 Dec 2020, and the event diabetes mellitus type 2 has a hospitalization date of 04 Dec 2020. Please confirm hospitalization dates or update as applicable. ' answered with 'will update once received' (Site from Safety).	Samantha Wieseler (b) (4)	(b) (4) 09 Jan 2021 16:50:03
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'will update once received' (Site from Safety).	Samantha Wieseler (b) (4)	(b) (4) 09 Jan 2021 16:49:52
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'will updated once received' (Site from Safety).	Samantha Wieseler (b) (4)	(b) (4) 09 Jan 2021 16:49:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'will update once received' (Site from Safety).	Samantha Wieseler (b) (4)	(b) (4) 09 Jan 2021 16:49:31
User opened query 'PV Query: Please provide signs and symptoms of COVID 19 (and when they started). If unknown, please state so. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 14:08:05
User opened query 'PV Query: The event COVID 19 has a hospitalization date of 03 Dec 2020, and the event diabetes mellitus type 2 has a hospitalization date of 04 Dec 2020. Please confirm hospitalization dates or update as applicable. ' (Site from Safety).		07 Jan 2021 14:06:37
User closed query 'PV Query: Kindly confirm the exact onset date of the reported event as one source doc states 02 Dec 2020 and another 01 Dec 2020' (Site from Safety).		29 Dec 2020 14:46:00
User closed query 'PV- Query. Kindly revise coded indication for Loratidine to seasonal allergy as reported. (currently entered as hypersensitivity)' (Site from Safety).		29 Dec 2020 14:45:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

2891 of 3715

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV-Query. Please consider adding seasonal influenza vaccine to concomitant med (vaccine) ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 14:45:32
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).		29 Dec 2020 14:45:20
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).		29 Dec 2020 14:45:04
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).		29 Dec 2020 14:44:54
User closed query 'PV Query: Please provide hospital discharge date. ' (Site from Safety).		29 Dec 2020 14:44:48
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'this has been updated, however subject did not have symptoms during time of convalescent visit due to the site not being made aware of hospitalization until after symptoms had resolved. ' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 17:06:29
Query 'PV Query: Kindly confirm the exact onset date of the reported event as one source doc states 02 Dec 2020 and another 01 Dec 2020' answered with 'Subject was diagnosed with Covid-19 on 30 Nov 2020, updated on this page. ' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 17:01:07
Query 'PV- Query. Kindly revise coded indication for Loratidine to seasonal allergy as reported. (currently entered as hypersensitivity)' answered with 'data updated' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:57:44

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV-Query. Please consider adding seasonal influenza vaccine to concomitant med (vaccine) ' answered with 'This is added on log line 2 of the conmed log' (Site from Safety).	Kelsey Kelley (b) (4)	28 Dec 2020 16:56:45
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' answered with 'updated these data points' (Site from Safety).	Kelsey Kelley (b) (4)	28 Dec 2020 16:54:13
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 'Medication log updated' (Site from Safety).	Kelsey Kelley (b) (4)	28 Dec 2020 16:51:49
Query 'PV Query: Please provide hospital discharge date. ' answered with 'Discharge date 07 DEC' (Site from Safety).	Kelsey Kelley (b) (4)	28 Dec 2020 16:51:23
Signature has been broken.	Kelsey Kelley (b) (4)	28 Dec 2020 16:50:52

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED TO REPORT SAE. SUBJECT WAS STILL IN HOSPITAL AT THE TIME OF THE CALL. SUBJECT WILL CALL AGAIN IN THE MORNING IF DISCHARGED AND SIGN A MEDICAL RELEASE FORM. Update 28 DEC: Medical records reviewed. In summary: subject diagnosed with covid on 30 Nov 2020. On 03 Dec-04 Dec he began to exhibit symptoms of Encephalopathy including lethargy and confusion. He was taken to the ER on 04 Dec and admitted. He utilized IV Dexamethasone and Remdesivir and at this time diagnosed with Diabetes mellitus type 2. his hgba1c was 12.5, admitting blood glucose 466. he was started on both long and short acting insulin, lisinopril, and simvastatin. on discharge he continued oral dexamethasone. Admission date 04 Dec, Discharge 07 Dec. he was on oxygen via nasal cannula <24 hours.' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:50:52
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 18:16:04
User opened query 'PV Query: Kindly confirm the exact onset date of the reported event as one source doc states 02 Dec 2020 and another 01 Dec 2020' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 13:49:16
User opened query 'PV- Query. Kindly revise coded indication for Loratidine to seasonal allergy as reported. (currently entered as hypersensitivity)' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 13:48:30
User opened query 'PV-Query. Please consider adding seasonal influenza vaccine to concomitant med (vaccine) ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 13:48:09
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 13:47:39

PRODUCTION RELEASE (v12.003
EAB) (1725)

2894 of 3715

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 13:47:14
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).		16 Dec 2020 13:47:01
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).		16 Dec 2020 13:46:41
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).		16 Dec 2020 13:46:22
User opened query 'PV Query: Please provide hospital discharge date. ' (Site from Safety).		16 Dec 2020 13:45:44
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'subject called to report SAE. Subject was still in hospital at the time of the call. Subject will call again in the morning if discharged and sign a medical release form.'	(b) (4) Linden DeBoer (b) (4) (b) (4)	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 21:58:11

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:21:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:48:22
User entered 'USA-US032-2020-mRNA-1273-P301000021'		29 Dec 2020 14:48:11

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:21:49
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 15:39:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 15:39:20
Data point term sent to Coder	System	28 Dec 2020 15:38:50
User entered 'Diabetes mellitus type 2'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:21:51
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:21:53
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'No (N)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:21:57
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per the source the start date of this AE was 3DEC20 please update' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:41:56
		13 Apr 2021 15:41:52
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
	(b) (4)	
Query 'Per the source the start date of this AE was 3DEC20 please update' answered with 'Updated to match' (Site from CRA).	Kelsey Kelley (b) (4)	11 Mar 2021 23:21:45
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	11 Mar 2021 23:21:35
	(b) (4)	
User entered '3 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	11 Mar 2021 23:21:35
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 20:27:51
DataPoint Verified.		09 Mar 2021 20:27:30
		09 Mar 2021 17:21:36
User opened query 'Per the source the start date of this AE was 3DEC20 please update' (Site from CRA).		
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '4 Dec 2020'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:21:59
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:01
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	10 Feb 2021 16:47:08
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	28 Dec 2020 15:38:16
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this AE and please note, it is not expected that a chronic condition would have an End date or would be indicated as resolved. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 01:16:57
Query 'Per DM CLR: Please review this AE and please note, it is not expected that a chronic condition would have an End date or would be indicated as resolved. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'date marked as end date was the date subject reported a new baseline (normal)' (Site from DM).	Samantha Wieseler (b) (4)	22 Mar 2021 18:24:27
User opened query 'Per DM CLR: Please review this AE and please note, it is not expected that a chronic condition would have an End date or would be indicated as resolved. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:16:06
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:04
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Feb 2021 16:47:08
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Feb 2021 16:47:08
User entered '10 Feb 2021' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	10 Feb 2021 16:47:08
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Feb 2021 16:46:35

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please provide the event end date, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:31:23
Query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please provide the event end date, when available. Please leave query open until information is available.' answered with 'Diabetes Mellitus will not change and is not expected to change hence why it is currently and for the foreseeable future ongoing. ' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:25:37
User opened query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please provide the event end date, when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:34:32
User closed query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please provide the event end date, when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:34:32

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please provide the event end date, when available. Please leave query open until information is available. ' answered with 'we will update accordingly, as subject is still experiencing symptoms' (Site from Safety). User opened query 'PV Query: If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please provide the event end date, when available. Please leave query open until information is available. ' (Site from Safety). User entered empty.	Samantha Wieseler (b) (4) (b) (4) (b) (4), (b) (6) Kelsey Kelley (b) (4) (b) (4)	19 Jan 2021 23:38:30 12 Jan 2021 10:53:52 28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:06
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 10:53:42
User opened query 'PV Query: Please provide the event end date, when available. ' (Site from Safety).		07 Jan 2021 14:05:50
User entered empty.	System	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:12
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:21
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:23
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	28 Dec 2020 16:56:02
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	28 Dec 2020 16:56:02
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	28 Dec 2020 15:38:16
User entered 'I'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:51
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User closed query 'PV Query: Per the discharge summary, the subject was admitted to the hospital on 03 Dec 2020. Please consider updating the admission date for the event of diabetes mellitus type 2 to 03 Dec 2020 as the hospitalization was prolonged due to this event.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:29:34
Query 'PV Query: Per the discharge summary, the subject was admitted to the hospital on 03 Dec 2020. Please consider updating the admission date for the event of diabetes mellitus type 2 to 03 Dec 2020 as the hospitalization was prolonged due to this event.' answered with 'data updated' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 16:12:21
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 16:12:14
User entered '3 Dec 2020' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	19 Feb 2021 16:12:14
User opened query 'PV Query: Per the discharge summary, the subject was admitted to the hospital on 03 Dec 2020. Please consider updating the admission date for the event of diabetes mellitus type 2 to 03 Dec 2020 as the hospitalization was prolonged due to this event.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 18:57:50
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	12 Feb 2021 19:55:44
User closed query 'PV Query: Thank you for confirming diagnosis date for diabetes as 04Dec2020. This was reported as the start date. Please consider updating hospital admission date to 03Dec2020 as the subject was admitted on this date for both events.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 14:35:01
Query 'PV Query: Thank you for confirming diagnosis date for diabetes as 04Dec2020. This was reported as the start date. Please consider updating hospital admission date to 03Dec2020 as the subject was admitted on this date for both events.' answered with 'The subject was admitted to the hospital on 04Dec2020. The start date of diabetes diagnosis is correct as entered. ' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	10 Feb 2021 16:46:14

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for confirming diagnosis date for diabetes as 04Dec2020. This was reported as the start date. Please consider updating hospital admission date to 03Dec2020 as the subject was admitted on this date for both events.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 21:20:43
User closed query 'PV Query: The event COVID 19 has a hospital admission date of 03 Dec 2020, and the event diabetes mellitus type 2 has an admission date of 04 Dec 2020. Please confirm which hospital admission date is correct, 03Dec or 04Dec, and update event accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:31:26
Query 'PV Query: The event COVID 19 has a hospital admission date of 03 Dec 2020, and the event diabetes mellitus type 2 has an admission date of 04 Dec 2020. Please confirm which hospital admission date is correct, 03Dec or 04Dec, and update event accordingly.' answered with 'as explained in the other AE subject was hospitalized on the 3rd and while there was diagnosed with diabetes. official diagnosis came on the 4th. ' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:26:31
User opened query 'PV Query: The event COVID 19 has a hospital admission date of 03 Dec 2020, and the event diabetes mellitus type 2 has an admission date of 04 Dec 2020. Please confirm which hospital admission date is correct, 03Dec or 04Dec, and update event accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:30:57
User entered '04 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	28 Dec 2020 16:55:49
User entered empty.	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:22:58
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '07 Dec 2020' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 16:55:49
User entered empty.	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:23:05
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Dec 2020 16:56:02
User entered empty.	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:23:07
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:23:09
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:23:10
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:23:12
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '0'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:23:15
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:23:17
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Not Related (NOT RELATED)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:23:18
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:24:26
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:24:28
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered 'I'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:24:30
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User closed query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:35:13
Query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available. ' answered with 'data updated' (Site from Safety).	Chelsie Nutsch (b) (4) (b) (4)	10 Feb 2021 16:47:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	10 Feb 2021 16:46:35
User opened query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available. ' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 21:19:02
User closed query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available. Please leave query open until outcome is achieved. ' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:31:32

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available. Please leave query open until outcome is achieved. ' answered with 'no new baseline is expected for the foreseeable future. recovering resolving is the remain the same' (Site from Safety).	Samantha Wieseler (b) (4)	21 Jan 2021 22:27:04
User opened query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available. Please leave query open until outcome is achieved. ' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:35:03
User closed query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 01:35:03
Query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available.' answered with 'subject has not reached a new baseline yet and is still in the recovering phase, will update when an update is available' (Site from Safety).	Samantha Wieseler (b) (4)	19 Jan 2021 23:39:07
User opened query 'PV Query: If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 10:54:50

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
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)	11 Jan 2021 14:50:32
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 'this will be ongoing' (Site from Safety).	Samantha Wieseler (b) (4)	09 Jan 2021 16:50:56
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)	07 Jan 2021 14:05:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:24:34
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:24:37
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
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. ' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 14:04:57
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)	07 Jan 2021 14:04:19
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Dec 2020 16:55:24
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	28 Dec 2020 16:55:24
User entered 'MEDICAL RECORDS REVIEWED. IN SUMMARY: SUBJECT DIAGNOSED WITH COVID ON 30 NOV 2020. ON 03 DEC-04 DEC HE BEGAN TO EXHIBIT SYMPTOMS OF ENCEPHALOPATHY INCLUDING LETHARGY AND CONFUSION. HE WAS TAKEN TO THE ER ON 04 DEC AND ADMITTED. HE UTILIZED IV DEXAMETHASONE AND REMDESIVIR AND AT THIS TIME DIAGNOSED WITH DIABETES MELLITUS TYPE 2. HIS HGBA1C WAS 12.5, ADMITTING BLOOD GLUCOSE 466. HE WAS STARTED ON BOTH LONG AND SHORT ACTING INSULIN, LISINOPRIL, AND SIMVASTATIN. ON DISCHARGE HE CONTINUED ORAL DEXAMETHASONE. ADMISSION DATE 04 DEC, DISCHARGE 07 DEC. HE WAS ON OXYGEN VIA NASAL CANNULA <24 HOURS.' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:55:24
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Dec 2020 15:38:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

2936 of 3715

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 15:38:16

US3032187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Dec 2020 16:56:02

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Acute sinusitis, LLT: Acute sinusitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 22:17:00
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 22:17:00
Data point term sent to Coder	System	05 Mar 2021 22:16:31
User entered 'acute sinusitis'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered '23 Feb 2021'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User entered empty.	System	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:41
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Un-verified.	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:22:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	11 Mar 2021 23:22:19
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'Yes (Y)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:43
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	(b) (4)	11 Mar 2021 23:22:47
User entered '3 Mar 2021' reason for change: Data Entry Error	System	11 Mar 2021 23:22:47
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	Kelsey Kelley (b) (4)	11 Mar 2021 23:22:47
DataPoint Un-verified.	(b) (4)	11 Mar 2021 23:22:19
User entered '10 Feb 2021' reason for change: Data Entry Error	System	11 Mar 2021 23:22:19
DataPoint Verified.	Kelsey Kelley (b) (4)	11 Mar 2021 23:22:19
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 20:27:30
	Linden DeBoer (b) (4)	05 Mar 2021 22:16:17
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User entered empty.	System	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'Not Related (NOT RELATED)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'Not Related (NOT RELATED)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'Not Applicable (NOT APPLICABLE)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'l'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
DataPoint Verified.		13 Apr 2021 15:44:33
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	11 Mar 2021 23:22:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Kelsey Kelley (b) (4)	11 Mar 2021 23:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Linden DeBoer (b) (4)	05 Mar 2021 22:16:17
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:27:30
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User entered '0'	System	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03
User entered 'I'	System	05 Mar 2021 22:16:17

US3032187

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:03

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User coded data point as SOC: Nervous system disorders, HLT: Encephalopathies, HLT: Encephalopathies toxic and metabolic, PT: Metabolic encephalopathy, LLT: Metabolic encephalopathy - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	12 Mar 2021 19:30:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 19:30:49
Data point term sent to Coder	System	12 Mar 2021 19:30:10
User entered 'metabolic encephalopathy'	Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '3 Dec 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
User entered empty.	System	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '5 Dec 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
User entered empty.	System	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'No (N)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'l'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
User entered '0'	System	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09
User entered 'I'	System	12 Mar 2021 19:29:39

US3032187

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:09

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	23 Mar 2021 17:10:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 17:10:38
Data point term sent to Coder	System	23 Mar 2021 16:54:28
User entered 'sore throat'	Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '19 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
User entered empty.	System	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '21 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
User entered empty.	System	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).		07 Apr 2021 11:42:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' answered with 'data updated' (Site from DM).	Chelsie Nutsch (b) (4)	06 Apr 2021 15:15:35
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	06 Apr 2021 15:15:28
	(b) (4)	
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 05:12:30
User entered 'None (NONE)'	Kelsey Kelley (b) (4)	23 Mar 2021 16:53:35
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
User entered '0'	System	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15
User entered 'I'	System	23 Mar 2021 16:53:35

US3032187

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:22:15

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	29 Mar 2021 14:20:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:20:03
Data point term sent to Coder	System	29 Mar 2021 14:18:56
User entered 'hypertension'	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '07 Dec 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
User entered empty.	System	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 19:45:00
User entered 'No (N)' reason for change: New Information	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 19:45:00
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.	(b) (4)	13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	06 Apr 2021 19:45:00
	(b) (4)	
User entered '6 Apr 2021' reason for change: New Information	Kelsey Kelley (b) (4)	06 Apr 2021 19:45:00
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
User entered empty.	System	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'l'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 19:45:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 19:45:00
Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:18:48
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
User entered '0'	System	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52
User entered 'I'	System	29 Mar 2021 14:18:48

US3032187

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:52

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Mar 2021 14:21:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:21:08
Data point term sent to Coder	System	29 Mar 2021 14:19:57
User entered 'hyperlipidemia'	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '07 Dec 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
User entered empty.	System	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	06 Apr 2021 19:44:28
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Apr 2021 19:44:28
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	06 Apr 2021 19:44:28
	(b) (4)	
User entered '6 Apr 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Apr 2021 19:44:28
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
	(b) (4)	
User entered empty.	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
User entered empty.	System	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Not Related (NOT RELATED)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'l'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 19:44:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 19:44:28
Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	29 Mar 2021 14:19:19
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
User entered '0'	System	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57
User entered 'I'	System	29 Mar 2021 14:19:19

US3032187

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:20:57

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.	(b) (4)	13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 19:48:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 19:48:23
Data point term sent to Coder	System	06 Apr 2021 19:47:54
User entered 'myalgia'	Kelsey Kelley (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '11 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
User entered empty.	System	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '24 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
User entered empty.	System	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
User entered '0'	System	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04
User entered '0'	System	06 Apr 2021 19:47:13

US3032187

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:04

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	(b) (4) 06 Apr 2021 19:48:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4) 06 Apr 2021 19:48:22
Data point term sent to Coder	System	06 Apr 2021 19:47:53
User entered 'Arthralgia'	Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '11 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
User entered empty.	System	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	9 Apr 2021 10:21:24
DataPoint Verified.		3 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '24 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
User entered empty.	System	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
User entered '0'	System	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24
User entered '0'	System	06 Apr 2021 19:47:48

US3032187

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:24

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
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) (b) (4) Coder Import (b) (4)	06 Apr 2021 19:49:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 19:49:29
Data point term sent to Coder	System	06 Apr 2021 19:48:55
User entered 'fatigue'	Kelsey Kelley (b) (4)	06 Apr 2021 19:48:29
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '11 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
User entered empty.	System	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '24 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
User entered empty.	System	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
User entered '0'	System	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31
User entered '0'	System	06 Apr 2021 19:48:29

US3032187

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:31

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Apr 2021 19:58:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 19:58:12
Data point term sent to Coder	System	06 Apr 2021 19:49:57
User entered 'Arthralgia'	Kelsey Kelley (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '14 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
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).	(b) (4)	06 Apr 2021 20:24:47
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	06 Apr 2021 20:24:47
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).	(b) (4)	
User entered '19:00' reason for change: Data Entry Error	System	06 Apr 2021 20:24:30
User entered empty.	Kelsey Kelley (b) (4)	06 Apr 2021 20:24:30
	(b) (4)	
	Kelsey Kelley (b) (4)	06 Apr 2021 19:49:10
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
User entered empty.	System	06 Apr 2021 20:24:47
User entered '14 Aug 2020 19:00'	System	06 Apr 2021 20:24:30
User entered empty.	System	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '23 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	06 Apr 2021 20:24:52
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	06 Apr 2021 20:24:52
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	06 Apr 2021 20:24:30
User entered '19:00' reason for change: Data Entry Error	System	06 Apr 2021 20:24:30
User entered empty.	Kelsey Kelley (b) (4)	06 Apr 2021 19:49:10
	(b) (4)	

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
User entered empty.	System	06 Apr 2021 20:24:52
User entered '23 Aug 2020 19:00'	System	06 Apr 2021 20:24:30
User entered empty.	System	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Related (RELATED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'None (NONE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '1' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 19:49:17
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 19:49:17
User entered '1'	(b) (4) Kelsey Kelley (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
DataPoint Verified.		13 Apr 2021 16:05:30
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:07:08
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
User entered '0'	System	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38
User entered '0'	System	06 Apr 2021 19:49:10

US3032187

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:50:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:38

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:50:15

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:01
DataPoint Verified.		09 Mar 2021 17:02:30
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:48:13

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 16:58:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 16:58:33
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	28 Dec 2020 16:57:54 28 Dec 2020 16:57:15
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 15:44:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 15:44:07
Data point term sent to Coder User entered 'loratidine'	System Kelsey Kelley (b) (4)	11 Aug 2020 20:49:08 11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
Signature has been broken.	(b) (4)	28 Dec 2020 16:57:15
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	28 Dec 2020 16:57:15
User signature succeeded.	(b) (4)	28 Sep 2020 17:28:40
User entered 'medical history: seasonal allergies'	Keith Vrbicky (b) (4)	11 Aug 2020 20:48:47
	Kelsey Kelley (b) (4)	
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '10'	Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'as needed (PRN)'	Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 10:11:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 20:48:47
User entered 'un UNK 2018'	Kelsey Kelley (b) (4) (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered '0'	Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered empty.	Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	Kelsey Kelley (b) (4)	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:48:47

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) (b) (4) Coder Import (b) (4)	01 Dec 2020 20:16:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 20:16:00
Data point term sent to Coder	System	01 Dec 2020 20:14:36
User entered 'Seasonal Influenza Vaccine'	Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Prophylaxis for Seasonal Influenza'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '.5'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'mL (mL)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'once (ONCE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	01 Dec 2020 20:14:25
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '25 Oct 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '0'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '25 Oct 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
User entered empty.	System	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
User entered empty.	System	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:37
User entered empty.	System	01 Dec 2020 20:14:25

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	28 Dec 2020 15:43:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Dec 2020 15:43:20
Data point term sent to Coder	System	28 Dec 2020 15:41:53
User entered 'Aspirin'	Kelsey Kelley (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'covid-19'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '81'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '07 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	10 Feb 2021 16:23:03
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	10 Feb 2021 16:23:03
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
	(b) (4)	
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:41:41
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).		17 Feb 2021 01:54:19
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	10 Feb 2021 16:23:03
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4)	10 Feb 2021 16:22:05
	(b) (4)	
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	10 Feb 2021 16:21:59
Signature has been broken.	Samantha Wieseler (b) (4)	10 Feb 2021 16:21:59
	(b) (4)	
User entered '09 Dec 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	10 Feb 2021 16:21:59
	(b) (4)	
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:15:25
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
	(b) (4)	
User entered empty.	Kelsey Kelley (b) (4)	28 Dec 2020 15:41:41
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
User entered '1'	System	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
User entered '1'	System	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:05
User entered '804 (804)'	System	28 Dec 2020 15:41:41

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	(b) (4) (b) (4) Coder Import (b) (4)	28 Dec 2020 15:44:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 15:44:20
Data point term sent to Coder	System	28 Dec 2020 15:42:54
User entered 'dexamethasone'	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'covid-19'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '4'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '07 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '17 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
User entered '1'	System	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
User entered '1'	System	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:10
User entered '804 (804)'	System	28 Dec 2020 15:42:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 12:38:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 12:38:16
Data point term sent to Coder	System	28 Dec 2020 15:43:57
User entered 'Insulin Aspart'	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'diabetes mellitus type 2'	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '12'	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'units'	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'three times daily (TID)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '04 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:17:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		17 Mar 2021 01:25:18
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'diabetes meds will continue on after AE. AE closed due to new normal' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:21:22
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 17:12:03
DataPoint Verified.		09 Mar 2021 17:11:03
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		28 Feb 2021 02:02:50
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	07 Jan 2021 19:17:03
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Dec 2020 15:43:42

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 12:33:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 12:33:24
Data point term sent to Coder	System	28 Dec 2020 15:44:57
User entered 'insulin detemir'	Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'diabetes mellitus type 2'	Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '20'	Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'units'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'twice daily (BID)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '04 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:18:02
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding A has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		17 Mar 2021 01:25:05
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'diabetes meds do not stop. AE closed due to new normal. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:21:46
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 17:15:16
DataPoint Verified.		09 Mar 2021 17:11:03
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		28 Feb 2021 02:02:42
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	07 Jan 2021 19:17:03
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Dec 2020 15:44:27

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4) 15 Mar 2021 18:23:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4) 15 Mar 2021 18:23:31
Data point term sent to Coder Coding entries removed.	System Samantha Wieseler	15 Mar 2021 18:22:52 (b) (4) 15 Mar 2021 18:22:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	(b) (4) 07 Jan 2021 19:17:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4) 28 Dec 2020 15:48:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4) 28 Dec 2020 15:48:20
Data point term sent to Coder	System	28 Dec 2020 15:47:01
User entered 'lisinopril'	Kelsey Kelley (b) (4)	(b) (4) 28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:18:10
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).		01 Apr 2021 01:19:01
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:07
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:47:03
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:14:47
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 01:24:35
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:22:58
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:22:52
User entered 'hypertension' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:22:52
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 17:13:42
DataPoint Verified.		09 Mar 2021 17:11:03

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 02:01:58
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'diabetes mellitus type 2'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '2.5'	Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'mg (mg)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '7 Dec 2020'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:18:12
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding A has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		17 Mar 2021 01:24:43
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'medication continues on AE closed due to new normal. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:22:36
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 17:15:25
DataPoint Verified.		09 Mar 2021 17:11:03
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding A has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		28 Feb 2021 02:02:32
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	07 Jan 2021 19:17:03
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Dec 2020 15:46:04

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Name of Medication](#)

Audit	User		Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	15 Mar 2021 18:24:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	15 Mar 2021 18:24:44
Data point term sent to Coder Coding entries removed.	System Samantha Wieseler	(b) (4)	15 Mar 2021 18:23:53 15 Mar 2021 18:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	(b) (4)	07 Jan 2021 19:17:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	28 Dec 2020 20:03:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4)	28 Dec 2020 20:03:28
Data point term sent to Coder	System		28 Dec 2020 15:49:02
User entered 'simvastatin'	Kelsey Kelley (b) (4)	(b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:18:20
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).		01 Apr 2021 01:19:10
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	29 Mar 2021 14:18:14
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:47:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	18 Mar 2021 21:14:47
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 01:24:52
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:23:17
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:23:10
User entered 'hyperlipidemia' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:23:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 17:15:39
DataPoint Verified.		09 Mar 2021 17:11:03

PRODUCTION RELEASE (v12.003
EAB) (1725)

3395 of 3715

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 02:02:08
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'diabetes mellitus type 2'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '20'	Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'once daily (QD)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Oral (ORAL)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '7 Dec 2020'	Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:18:22
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		17 Mar 2021 01:24:53
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'ae stopped due to new normal. medication will continue' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Mar 2021 18:23:46
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 17:15:45
DataPoint Verified.		09 Mar 2021 17:11:03
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		28 Feb 2021 02:02:25
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	07 Jan 2021 19:17:03
User entered 'Yes (Y)'	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	Kelsey Kelley (b) (4)	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Dec 2020 15:48:18

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	28 Dec 2020 15:59:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 15:59:21
Data point term sent to Coder	System	28 Dec 2020 15:58:08
User entered 'dexamethasone'	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'covid-19'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '6'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '4 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '6 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
User entered '1'	System	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
User entered '1'	System	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:15
User entered '804 (804)'	System	28 Dec 2020 15:57:52

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	(b) (4) 28 Dec 2020 16:00:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	(b) (4) 28 Dec 2020 16:00:21
Data point term sent to Coder	System	28 Dec 2020 16:00:09
User entered 'Remdesivir'	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'covid-19'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '200'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '4 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '4 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
User entered empty.	System	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
User entered empty.	System	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:18
User entered empty.	System	28 Dec 2020 15:59:44

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Dec 2020 16:03:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Dec 2020 16:03:21
Data point term sent to Coder	System	28 Dec 2020 16:02:10
User entered 'oxygen'	Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'covid-19'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '2'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'liters'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'other (OTHER)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Continuous'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Nasal (NASAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '04 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '5 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
User entered empty.	System	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
User entered empty.	System	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:22
User entered empty.	System	28 Dec 2020 16:01:57

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	28 Dec 2020 16:05:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Dec 2020 16:05:21
Data point term sent to Coder	System	28 Dec 2020 16:04:13
User entered 'Remdesivir'	Kelsey Kelley (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'covid-19'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '100'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	(b) (4)	07 Jan 2021 19:17:03
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '05 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered '06 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
DataPoint Verified.		09 Mar 2021 17:11:03
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:03
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
User entered '1'	System	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
User entered '1'	System	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:25:26
User entered '804 (804)'	System	28 Dec 2020 16:03:20

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 04:37:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 04:37:59
Data point term sent to Coder	System	05 Mar 2021 22:19:43
User entered 'amoxicillin-clavulanate'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered 'acute sinusitis'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered '875/125'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered 'mg (mg)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered 'twice daily (BID)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered 'Oral (ORAL)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered empty.	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered '23 Feb 2021'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered '0'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:19:07
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	11 Mar 2021 23:23:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	11 Mar 2021 23:23:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	05 Mar 2021 22:19:40
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:19:08
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Un-verified.	(b) (4)	
	Kelsey Kelley (b) (4)	11 Mar 2021 23:23:35
User entered '1 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	11 Mar 2021 23:23:35
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered empty.	Linden DeBoer (b) (4)	05 Mar 2021 22:19:40
	(b) (4)	

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:11:03
User entered 'No (N)'	Linden DeBoer (b) (4) (b) (4)	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User entered '2'	System	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User entered '1'	System	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:51:51
User entered '804 (804)'	System	05 Mar 2021 22:19:40

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:19:43
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Mar 2021 16:55:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Mar 2021 16:55:38
Data point term sent to Coder	System	23 Mar 2021 16:54:29
User entered 'prednisone'	Kelsey Kelley (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:19:55
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:19:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'sore throat'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:01
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '20'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:03
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:09
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:11
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 21:52:02
DataPoint Verified.		3 Apr 2021 16:20:19
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:21
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '19 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:25
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:57
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered '21 Mar 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
DataPoint Verified.		13 Apr 2021 16:20:59
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:37:33
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
User entered '1'	System	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
User entered '1'	System	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:50:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:52:02
User entered '804 (804)'	System	23 Mar 2021 16:54:24

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:50:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:01
DataPoint Verified.	(b) (4)	15 Apr 2021 18:42:50
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
DataPoint Un-verified.	(b) (4)	
	Chelsie Nutsch (b) (4)	12 Mar 2021 19:33:06
Signature has been broken.	(b) (4)	
	Chelsie Nutsch (b) (4)	12 Mar 2021 19:33:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Chelsie Nutsch (b) (4)	12 Mar 2021 19:33:06
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:02:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 17:28:40
User entered 'No (N)'	(b) (4)	
	Kelsey Kelley (b) (4)	11 Aug 2020 20:48:07
	(b) (4)	

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:50:15

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Chelsie Nutsch (b) (4)	12 Mar 2021 19:38:21
User entered '4 Dec 2020'	(b) (4)	
	Chelsie Nutsch (b) (4)	12 Mar 2021 19:33:36
	(b) (4)	

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:50:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Blood work'	(b) (4) Chelsie Nutsch (b) (4)	12 Mar 2021 19:33:36

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Adverse Event (AE)'	(b) (4) Chelsie Nutsch (b) (4)	12 Mar 2021 19:33:36

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:50:15

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	12 Mar 2021 19:33:36

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:50:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:35
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '30 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:34:02

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:50:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:35
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Covid-19 PCR nasal swab'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:34:02

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:35
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Adverse Event (AE)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:34:02

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:50:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:35
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:34:02

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:50:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:36
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '03 Dec 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:40:29

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:50:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:36
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'CT Head without Contrast'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:40:29

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:36
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Adverse Event (AE)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:40:29

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:50:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:36
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:40:29

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:50:15

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:39
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '03 Dec 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:40:45

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:50:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:39
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Chest X-ray'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:40:45

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:50:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:39
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'Adverse Event (AE)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:40:45

US3032187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:50:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:56:39
DataPoint Verified.		15 Apr 2021 18:43:03
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	12 Mar 2021 19:40:45

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered '08/Dec/2020 11:45'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered '11/Dec/2020 09:59'	(b) (4) System	11 Dec 2020 17:59:27

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		29 Dec 2020 14:48:39
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:59:27

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
User entered '29/Dec/2020 09:48'	(b) (4) System	29 Dec 2020 14:48:59

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		19 Jan 2021 13:14:42
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
User entered 'l'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:48:59

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '19/Jan/2021 13:14'	(b) (4) System	19 Jan 2021 13:14:57

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:31:45
User entered '1'		19 Jan 2021 13:14:57

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered '22/Jan/2021 16:31'	(b) (4) System	22 Jan 2021 16:32:02

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Feb 2021 14:41:32
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:32:02

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '11/Feb/2021 09:41'	(b) (4) System	11 Feb 2021 14:41:27

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:41:32
User entered 'I'		11 Feb 2021 14:41:27

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
User entered '12/Feb/2021 10:38'	(b) (4) System	12 Feb 2021 15:38:45

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:38:51
User entered '1'		12 Feb 2021 15:38:45

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '19/Feb/2021 11:38'	(b) (4) System	19 Feb 2021 16:38:47

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:36:22
User entered '1'		19 Feb 2021 16:38:47

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered '22/Feb/2021 10:36'	(b) (4) System	22 Feb 2021 15:37:02

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:37:02

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:43:50
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '12/Mar/2021 07:09'	(b) (4) System	12 Mar 2021 15:09:34

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:43:50
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 15:09:34

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 14:50:15

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '15/Mar/2021 08:16'	(b) (4) System	15 Mar 2021 12:17:04

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:43:53
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:17:04

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'USA-US032-2020-MRNA-1273-P301000021'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Yes (Y)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'No (N)'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Keith'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 16:45:09
User entered 'Vrbicky'	System	08 Dec 2020 16:44:56

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 08:11:04
Reviewed for Safety.		11 Dec 2020 17:59:14
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
User entered 'US'	(b) (4) System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	15 Mar 2021 12:17:04
User entered '10'	System	12 Mar 2021 15:09:34
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:25:16
	(b) (4)	
User entered '9'	System	22 Feb 2021 15:37:02
Signature has been broken.	System	19 Feb 2021 16:38:47
User entered '8'	System	19 Feb 2021 16:38:47
User signature succeeded.	Keith Vrbicky (b) (4)	12 Feb 2021 19:55:44
	(b) (4)	
User entered '7'	System	12 Feb 2021 15:38:45
Signature has been broken.	System	11 Feb 2021 14:41:27
User entered '6'	System	11 Feb 2021 14:41:27
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:50:28
	(b) (4)	
User entered '5'	System	22 Jan 2021 16:32:02
Signature has been broken.	System	19 Jan 2021 13:14:57
User entered '4'	System	19 Jan 2021 13:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:17:04
	(b) (4)	
Signature has been broken.	System	29 Dec 2020 14:48:59
User entered '3'	System	29 Dec 2020 14:48:59
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:09:42
	(b) (4)	
Signature has been broken.	System	11 Dec 2020 17:59:27
User entered '2'	System	11 Dec 2020 17:59:27
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:47:58
	(b) (4)	
User entered '1'	System	08 Dec 2020 16:45:26

US3032187

Folder: SAE USA-US032-2020-MRNA-1273-P301000021

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 14:50:15

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:42:12
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:14:47
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:17:04