

US3262145 (Prod: AB Clinical Trials - Hunt - PPDS)

Generated By: KC Joubran

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US3262145

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 16:41:00

Generated On: 09 Jun 2021 16:18:25

Participant ID

US3262145

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

US3262145

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 22:52:07

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Date of Informed Consent (*dd MMM yyyy*) 08 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3262145

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 22:52:07

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 22:52:07

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Condition	DYSLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Condition	TYPE 2 DIABETES
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)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:05 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 15:05
Height (<i>xxx.x</i>)	60 in
Weight (<i>xxx.x</i>)	232.0 lb
BMI (<i>xxx.x</i>)	45.40413 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)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

08 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:52:07

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:52:07

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 08 AUG 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 143453

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

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 (<i>dd MMM yyyy</i>)	08 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:05 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 15:05
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	95 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

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 (<i>dd MMM yyyy</i>)	08 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:52 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 15:52
Temperature (<i>xxx.x</i>)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

08 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

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 AUG 2020

What was the treatment time? (00:00-23:59) 15:22 (24 HR)

Treatment Date and Time (derived) 08 AUG 2020 15:22

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	08 AUG 2020
Collection time (<i>00:00-23:59</i>)	15:16 (24 HR)
Collection date and time (derived)	08 AUG 2020 15:16

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Collection date (<i>dd MMM yyyy</i>)			08 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:11	08 AUG 2020 15:11
Nasopharyngeal Swab 2	No		

US3262145

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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 99.0 °F

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

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

PC Time Stamp 08 AUG 2020 15:54

PC Open Date & Time 08 AUG 2020 15:42

PC Close Date & Time 08 AUG 2020 18:12

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.2 °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	08 AUG 2020 19:21
PC Open Date & Time	08 AUG 2020 19:07
PC Close Date & Time	09 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 AUG 2020 12:39
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 AUG 2020 12:33
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 AUG 2020 12:05
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 AUG 2020 12:22
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 AUG 2020 12:05
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 AUG 2020 12:39
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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 AUG 2020 15:54

PC Open Date & Time

08 AUG 2020 15:42

PC Close Date & Time

08 AUG 2020 18:12

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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 AUG 2020 19:22

PC Open Date & Time

08 AUG 2020 19:07

PC Close Date & Time

09 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

16

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	09 AUG 2020 12:40
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

15

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	10 AUG 2020 12:34
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

15

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

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 AUG 2020 12:06

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

10

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

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

12 AUG 2020 12:23

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

5

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

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

13 AUG 2020 12:06

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

12

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

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

14 AUG 2020 12:40

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

No
Yes

PC Time stamp	08 AUG 2020 15:55
PC Open Date & Time	08 AUG 2020 15:42
PC Close Date & Time	08 AUG 2020 18:12

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

No
Yes

PC Time stamp	08 AUG 2020 19:23
PC Open Date & Time	08 AUG 2020 19:07
PC Close Date & Time	09 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	09 AUG 2020 12:41
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	10 AUG 2020 12:35
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	11 AUG 2020 12:06
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 12:23
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	13 AUG 2020 12:06
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	14 AUG 2020 12:40
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 8

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

Yes

No

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

5

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

PC Time stamp

15 AUG 2020 14:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT	DAY 9
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
PC Time stamp	16 AUG 2020 14:07
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

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	15 AUG 2020 14:31
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

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	16 AUG 2020 14:07
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3262145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

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 (<i>dd MMM yyyy</i>)	05 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:05 (24 HR)
Vital Signs Date and Time (derived)	05 SEP 2020 15:05
Temperature (<i>xxx.x</i>)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

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 (<i>dd MMM yyyy</i>)	05 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:53 (24 HR)
Vital Signs Date and Time (derived)	05 SEP 2020 15:53
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3262145

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

05 SEP 2020

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

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

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) 05 SEP 2020

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

Treatment Date and Time (derived) 05 SEP 2020 15:23

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

US3262145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 05 SEP 2020

Collection time (*00:00-23:59*) 15:10 (24 HR)

Collection date and time (derived) 05 SEP 2020 15:10

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Collection date (<i>dd MMM yyyy</i>)			05 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:07	05 SEP 2020 15:07
Nasopharyngeal Swab 2	No		

US3262145

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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 05 SEP 2020 16:00

PC Open Date & Time 05 SEP 2020 15:43

PC Close Date & Time 05 SEP 2020 18:13

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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 05 SEP 2020 21:28
PC Open Date & Time 05 SEP 2020 19:08
PC Close Date & Time 06 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

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 96.1 °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 06 SEP 2020 12:06

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	07 SEP 2020 12:50
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 12:05
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 SEP 2020 13:01
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 SEP 2020 12:48
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 SEP 2020 12:03
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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	05 SEP 2020 16:00
PC Open Date & Time	05 SEP 2020 15:43
PC Close Date & Time	05 SEP 2020 18:13

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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	05 SEP 2020 21:28
PC Open Date & Time	05 SEP 2020 19:08
PC Close Date & Time	06 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

15

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

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

06 SEP 2020 12:07

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

12

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

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

07 SEP 2020 12:51

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

15

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

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

08 SEP 2020 12:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	09 SEP 2020 13:01
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 6

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

10 SEP 2020 12:49

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

11 SEP 2020 12:03

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

No

Yes

PC Time stamp	05 SEP 2020 16:01
PC Open Date & Time	05 SEP 2020 15:43
PC Close Date & Time	05 SEP 2020 18:13

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

No

Yes

PC Time stamp	05 SEP 2020 21:29
PC Open Date & Time	05 SEP 2020 19:08
PC Close Date & Time	06 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 12:07
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 12:51
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 12:04
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 13:02
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 12:49
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

PC Time Stamp

12 SEP 2020 15:48

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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

PC Time Stamp 13 SEP 2020 13:44

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

12 SEP 2020 15:48

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time Stamp

13 SEP 2020 13:44

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:18:25

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

14 SEP 2020 12:01

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

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

12 SEP 2020 15:48

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 9

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

13 SEP 2020 13:44

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

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

12 SEP 2020 15:48

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 9

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

13 SEP 2020 13:44

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

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	12 SEP 2020 15:48
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

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	13 SEP 2020 13:44
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3262145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:52:07

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 06 OCT 2020

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

Folder OID VISIT3

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	06 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:25 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 15:25
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3262145

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

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.

US3262145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 06 OCT 2020

Collection time (*00:00-23:59*) 15:30 (24 HR)

Collection date and time (derived) 06 OCT 2020 15:30

US3262145

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:52:35

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 64

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 <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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 106

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 110

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

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

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

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

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

Fever (Temperature \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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 117

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

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

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

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

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

Fever (Temperature \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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 DEC 2020 14:53:50
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 <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 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"/>
Have 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	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 DEC 2020 09:23:52
Patient Cloud Open Date & Time	14 DEC 2020 00:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 12:44:30

Patient Cloud Open Date & Time 21 DEC 2020 00:01

Patient Cloud Close Date & Time 25 DEC 2020 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 29 DEC 2020 17:48:07

Patient Cloud Open Date & Time 28 DEC 2020 00:01

Patient Cloud Close Date & Time 01 JAN 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 04 JAN 2021 18:54:37

Patient Cloud Open Date & Time 04 JAN 2021 00:01

Patient Cloud Close Date & Time 08 JAN 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

11 JAN 2021 07:16:59

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 07:39:48
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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	25 JAN 2021 12:08:52
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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	01 FEB 2021 07:07:39
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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	09 FEB 2021 13:49:44
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 15 FEB 2021 09:44:45

Patient Cloud Open Date & Time 15 FEB 2021 00:01

Patient Cloud Close Date & Time 19 FEB 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 FEB 2021 13:09:10
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

02 MAR 2021 13:37:34

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 <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	08 MAR 2021 09:58:27
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 222

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 MAR 2021 08:25:45
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 08:35:32
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	05 APR 2021 09:28:31
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 <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	12 APR 2021 09:21:48
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 <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	19 APR 2021 07:25:55
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 <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	26 APR 2021 10:50:09
Patient Cloud Open Date & Time	26 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	07 MAY 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 320

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	02 JUL 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 341

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

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

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

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

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

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

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#) 06 AUG 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 369

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	16 AUG 2021 00:01
Patient Cloud Close Date & Time	20 AUG 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#) 27 AUG 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	06 SEP 2021 00:01
Patient Cloud Close Date & Time	10 SEP 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 411

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

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

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

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

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

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

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 08 OCT 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 432

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2021 00:01
Patient Cloud Close Date & Time	22 OCT 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 446

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 460

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	08 NOV 2021 00:01
Patient Cloud Close Date & Time	12 NOV 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	06 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	21 JAN 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	04 FEB 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 572

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#) 11 MAR 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 600

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	04 APR 2022 00:01
Patient Cloud Close Date & Time	08 APR 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 614

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	18 APR 2022 00:01
Patient Cloud Close Date & Time	22 APR 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	16 MAY 2022 00:01
Patient Cloud Close Date & Time	20 MAY 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	23 MAY 2022 00:01
Patient Cloud Close Date & Time	27 MAY 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2022 00:01
Patient Cloud Close Date & Time	17 JUN 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 691

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2022 00:01
Patient Cloud Close Date & Time	08 JUL 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#) 22 JUL 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2022 00:01
Patient Cloud Close Date & Time	29 JUL 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 726

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 05 AUG 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 740

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 19 AUG 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2022 00:01
Patient Cloud Close Date & Time	26 AUG 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2022 00:01
Patient Cloud Close Date & Time	09 SEP 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2022 00:01
Patient Cloud Close Date & Time	16 SEP 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2022 00:01
Patient Cloud Close Date & Time	23 SEP 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2022 00:01
Patient Cloud Close Date & Time	30 SEP 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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°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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	03 OCT 2022 00:01
Patient Cloud Close Date & Time	07 OCT 2022 23:59

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

DAY 796

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

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

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

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

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

- Fever (Temperature \geq 100.4°F/38°C) _____
- Chills _____
- Cough _____
- Shortness of breath _____
- Difficulty breathing _____
- Fatigue _____
- Muscle aches _____
- Body aches _____
- Headache _____
- New loss of taste _____
- New loss of smell _____
- Sore throat _____
- Congestion _____
- Runny nose _____
- Nausea _____
- Vomiting _____
- Diarrhea _____

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

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

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3262145

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:18:25

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		02 MAR 2021 13:37:20

US3262145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:40:53

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:40:53

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 MAR 2021

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

Folder OID VISIT4

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 02 MAR 2021

Time of assessment (00:00-23:59) 10:35 (24 HR)

Vital Signs Date and Time (derived) 02 MAR 2021 10:35

Temperature (xxx.x) 99.0 F

Route of measurement Oral
Axillary
Other

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) 133 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 84 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3262145

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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.

US3262145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 02 MAR 2021

Collection time (*00:00-23:59*) 10:40 (24 HR)

Collection date and time (derived) 02 MAR 2021 10:40

US3262145

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

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 _____

US3262145

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 16:41:01

Generated On: 09 Jun 2021 16:18:25

Date of Contact	14 DEC 2020
Time of Contact	12:00
Date and Time of Contact (derived)	14 DEC 2020 12:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/> Clinical Visit - Unscheduled <input type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Symptom Day

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	38.9 C
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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 type="radio"/>
	Mild <input checked="" 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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	102.2 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 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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	100.2 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 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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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 type="radio"/>
	Mild <input checked="" 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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	100.6 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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 93 %

O2 Saturation Units %

Temperature 100.1 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	91 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	101 F
-------------	-------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	93 %
---------------	------

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	92 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.7 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	93 %
---------------	------

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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 24 DEC 2020

Assessment Not Done False

O2 Saturation 92 %

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 type="radio"/>
Mild	<input type="radio"/>
Moderate	<input checked="" type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	25 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Symptom Day

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

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	26 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	27 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input 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"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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 28 DEC 2020

Assessment Not Done False

O2 Saturation 97 %

O2 Saturation Units %

Temperature 97.8 F

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Cough

None	<input type="radio"/>
Mild	<input 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Symptom Day

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

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

	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	29 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.2 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 16:41:01

Generated On: 09 Jun 2021 16:18:25

Date of Visit 14 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 14 DEC 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 1

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 16:41:01

Generated On: 09 Jun 2021 16:18:25

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 _____ 15 DEC 2020
End Date _____ 26 DEC 2020
Oxygen Saturation _____ 91 %

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 _____

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 16:41:01

Generated On: 09 Jun 2021 16:18:25

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

Ventilator Support:

High-Flow Oxygen? Yes No

Start Date 19 DEC 2020

End Date 25 DEC 2020

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 _____

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 16:41:01

Generated On: 09 Jun 2021 16:18:25

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 _____

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 16:41:02

Generated On: 09 Jun 2021 16:18:25

[Generate Next COVID-19 Assessment](#)

Yes

No

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 16:42:36

Generated On: 09 Jun 2021 16:18:25

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 DEC 2020
Day 5	Yes	18 DEC 2020
Day 7	Yes	20 DEC 2020
Day 9	Yes	22 DEC 2020
Day 14	Yes	27 DEC 2020
Day 21	Yes	03 JAN 2021
Day 28	Yes	13 JAN 2021

US3262145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:42:36

Generated On: 09 Jun 2021 16:18:25

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 DEC 2020

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

Folder OID SICKD1

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:42:36

Generated On: 09 Jun 2021 16:18:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	12:25 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 12:25
Height (<i>xxx.x</i>)	60 in
Weight (<i>xxx.x</i>)	
Temperature (<i>xxx.x</i>)	38.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	111 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3262145

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:42:36

Generated On: 09 Jun 2021 16:18:25

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3262145

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 28 Apr 2021 16:42:36

Generated On: 09 Jun 2021 16:18:25

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

14 DEC 2020

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:41:01

Generated On: 09 Jun 2021 16:18:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:41:01

Generated On: 09 Jun 2021 16:18:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	11:25 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 11:25
Height (<i>xxx.x</i>)	60 in
Weight (<i>xxx.x</i>)	229.8 lb
Temperature (<i>xxx.x</i>)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:41:01

Generated On: 09 Jun 2021 16:18:25

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3262145

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 28 Apr 2021 16:41:01

Generated On: 09 Jun 2021 16:18:25

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

13 JAN 2021

US3262145

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 28 JAN 2021

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

Folder OID UNBLND_DECIDE

US3262145

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Date of updated informed consent (<i>dd MMM yyyy</i>)	28 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>)	28 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

US3262145

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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

US3262145

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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)	28 JAN 2021
Time of assessment (00:00-23:59)	08:39 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 08:39
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3262145

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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)	28 JAN 2021
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 09:21
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3262145

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3262145

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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) 28 JAN 2021

What was the treatment time? (00:00-23:59) 08:51 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 08:51

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

US3262145

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 28 JAN 2021

Collection time (*00:00-23:59*) 08:44 (24 HR)

Collection date and time (derived) 28 JAN 2021 08:44

US3262145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 28 JAN 2021

Collection time (*00:00 - 23:59*) 08:42

Collection Date and Time (derived) 28 JAN 2021 08:42

US3262145

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 MAR 2021

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

Folder OID OLD29

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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 (<i>dd MMM yyyy</i>)	02 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:35 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 10:35
Temperature (<i>xxx.x</i>)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 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>)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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 (<i>dd MMM yyyy</i>)	02 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:14 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 11:14
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3262145

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*)

02 MAR 2021

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

US3262145

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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) 02 MAR 2021

What was the treatment time? (00:00-23:59) 10:44 (24 HR)

Treatment Date and Time (derived) 02 MAR 2021 10:44

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

US3262145

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3262145

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3262145

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:16 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 10:16
Temperature (<i>xxx.x</i>)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3262145

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

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.

US3262145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 30 MAR 2021

Collection time (*00:00-23:59*) 10:19 (24 HR)

Collection date and time (derived) 30 MAR 2021 10:19

US3262145

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 May 2021 19:55:00

Generated On: 09 Jun 2021 16:18:25

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:41:00

Generated On: 09 Jun 2021 16:18:25

AEID USA-US069-2020-MRNA-1273-P30
1000003

Adverse event SYMPTOMATIC RT-PCR
CONFORMED COVID19
INFECTION

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 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) 29 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 True

Hospital Admission Date (dd MMM yyyy) 19 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 25 DEC 2020

Admitted to ICU? Yes
No

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	Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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

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PATIENT CAME IN DECEMBER 14TH FOR ILLNESS VISIT, AND HIS SYMPTOMS SEEMS TO IMPROVE EXCEPT FOR HIS O2 SAT AND TEMPS. HIS COUGH ACTUALLY WENT FROM MILD TO MODERATE, AND HE DEVELOPED SEVERE SHORTNESS OF BREATH AND DIFFICULTY BREATHING THAT I INSTRUCTED IF THIS HAPPENS GO TO ER. HE WENT ON 12/19/20 AND WAS PLACED ON 3LITERS OF SUPPLEMENTAL OXYGEN. HE ALSO WAS GIVEN EXPERIMENTAL MEDICATION REMDESIVIR THAT WE WILL ENTER ON DECEMBER 24TH AS IF WE DO NOW, THE SYSTEM WILL QUERY. HE IS NOT IN THE ICU BUT IN THE COVID UNIT. I HAVE BEEN SPEAKING TO THE PATIENT AND GETTING VITALS WHILE HE IS IN THE HOSPITAL AND I AM HAVING HIM COLLECT SALIVA SAMPLES WHILE THERE AS WELL AS I INSTRUCTED HIM TO TAKE HIS KIT WITH HIM IN CASE HE NEEDED TO BE HOSPITALIZED. PORTABLE CHEST XRAY WAS COMPLETED 12/19/2020 FINDINGS - MODERATE PERIPHERAL GROUNDGLASS AND AIRSPACE PACITIES WHICH CORRELATE WITH COVID 19 PNEUMONIA NORMAL HEART SIZE WITH ACCENTUATION FUE TO LOW VOLMES NO PLEURAL EFFUSION NO PNEUMOTHORAX NO ACUTE BONY LESION

Serious Adverse Event Derived (CSA Programming Field Ony)

1

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:41:00

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AEID

Adverse event

WHOLE BODY MUSCLE ACHES

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 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)

13 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious?

Yes
No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

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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 checked="" type="radio"/> Related <input 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: _____	
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)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 16:41:00

Generated On: 09 Jun 2021 16:18:25

AEID

Adverse event

NON MIGRAINE HEADACHE

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)

12 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)

13 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 16:41:00

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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 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: _____	
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)	_____

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 16:41:00

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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)	12 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)	13 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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 16:41:00

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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 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: _____	
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)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 16:41:00

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AEID

Adverse event

HARDNESS AT INJECTION SITE

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)

15 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)

16 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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 16:41:00

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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 checked="" type="radio"/> Related <input 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: _____	
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)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 20:30:59

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

Yes

No

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 20:23:02

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Name of Medication METOPROLOL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

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 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

Name of Medication ATORVASTATIN

Prophylaxis Yes
No

Indication DYSLIPIDEMIA

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

	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 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

Name of Medication BUPROPRION

Prophylaxis Yes
No

Indication ANXIETY

Dose per administration 300

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

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 2015

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 20:23:02

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Name of Medication METFORMIN

Prophylaxis Yes
No

Indication TYPE 2 DIABETES

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication CARDIO PROTECTIVE

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

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 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

Name of Medication REMDESIVIR

Prophylaxis Yes
No

Indication SEVERE SYMPTOMATIC
COVID19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

	Intraocular	<input type="checkbox"/>
	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	20 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)	24 DEC 2020
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/> No <input 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

Name of Medication SUPPLEMENTAL OXYGEN

Prophylaxis Yes
No

Indication SYMPTOMATIC RT PCR
CONFIRMED COVID19
INFECTION

Dose per administration 3

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

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

467 of 3057

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

	Intraocular	<input type="checkbox"/>
	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) 19 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 24 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

Name of Medication AZITHROMYCIN

Prophylaxis Yes
No

Indication SYMPTOMATIC RT PCR
CONFIRMED COVID 19
INFECTION

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

469 of 3057

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

	Intraocular	<input type="checkbox"/>
	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) 19 DEC 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 24 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

Name of Medication CEFTRIAXONE

Prophylaxis Yes
No

Indication SYMPTOMATIC RT PCR
CONFIRMED COVID 19
INFECTION

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

471 of 3057

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 20:23:02

Generated On: 09 Jun 2021 16:18:25

Intraocular	<input type="radio"/>
Intramuscular	<input 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 checked="" 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)	19 DEC 2020
--------------------------	-------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020
--	-------------

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"/>

US3262145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 20:10:32

Generated On: 09 Jun 2021 16:18:25

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3262145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 20:10:32

Generated On: 09 Jun 2021 16:18:25

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
19 DEC 2020	CHEST AP PORTABLE	Adverse Event	

US3262145

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:18:25

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

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

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

US3262145

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:18:25

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

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

SAEID	USA-US069-2020-MRNA-1273-P30 1000003
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

SAEID	USA-US069-2020-MRNA-1273-P301000003
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	22/DEC/2020 15:41
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

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

SAEID	USA-US069-2020-MRNA-1273-P301000003
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	28/DEC/2020 17:25
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

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

SAEID	USA-US069-2020-MRNA-1273-P301000003
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	06/JAN/2021 20:42
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

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

SAEID	USA-US069-2020-MRNA-1273-P301000003
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/FEB/2021 14:39
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

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

SAEID	USA-US069-2020-MRNA-1273-P301000003
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/FEB/2021 10:40
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

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 16:42:37

Generated On: 09 Jun 2021 16:18:25

SAEID	USA-US069-2020-MRNA-1273-P301000003
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	ATOYA
Investigator's Last Name	ADAMS
Site Address: Street	2121 E. FLAMINGO ROAD
Site Address: City	LAS VEGAS
Site Address: State	NV
Site Address: Postal Code	89119
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3262145 (Prod: AB Clinical Trials - Hunt - PPDS)

US3262145

Form: Participant Creation

Generated On: 09 Jun 2021 16:18:25

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'US3262145'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 22:05:27

US3262145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:09:44

US3262145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 22:05:28

US3262145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:09:44

US3262145

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'SCRN'	System	10 Aug 2020 14:09:44

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 22:05:29

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 14:10:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 14:10:14
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	10 Aug 2020 14:10:14
User entered '56' reason for change: Data Entry Error	Daisy Langarica (b) (4)	10 Aug 2020 14:10:14
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 14:10:08
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	10 Aug 2020 14:10:08
User entered empty.	Daisy Langarica (b) (4)	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
User entered 'YEARS'	System	10 Aug 2020 14:10:14
User entered empty.	System	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
User entered '56'	System	08 Aug 2020 22:37:33

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered 'Male (M)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered '1'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:10:08

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
	[REDACTED]	
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	10 Aug 2020 14:10:08
	(b) (4)	

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	10 Aug 2020 14:10:08
	(b) (4)	

US3262145

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:25

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
	[REDACTED]	
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
	(b) (4)	
User entered '0'	Daisy Langarica (b) (4)	10 Aug 2020 14:10:08
	(b) (4)	

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
	[REDACTED]	
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
	(b) (4)	
User entered '08 Aug 2020'	Daisy Langarica (b) (4)	08 Aug 2020 22:37:33
	(b) (4)	

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User entered 'Aug 2020'	System	08 Aug 2020 22:37:33

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User entered '2020'	System	08 Aug 2020 22:37:33

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Amendment 2 (2)'	Daisy Langarica (b) (4)	08 Aug 2020 22:37:33

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	08 Aug 2020 22:37:33

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	08 Aug 2020 22:37:33
	(b) (4)	

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered empty.	Daisy Langarica (b) (4) (b) (4)	08 Aug 2020 22:37:33

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	08 Aug 2020 22:37:33

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 22:05:28

US3262145

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:33:59
User entered '1'	System	08 Aug 2020 22:37:36

US3262145

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 06:33:59
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	08 Aug 2020 22:37:36

US3262145

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:18:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:21

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:16:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:16:22
Data point term sent to Coder	System	10 Aug 2020 14:11:34
User entered 'hypertension'	Daisy Langarica (b) (4)	10 Aug 2020 14:10:39

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'un UNK 2010'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:39

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:39

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:39

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:39
	(b) (4)	

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:39

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'Jan 2010'	System	10 Aug 2020 14:10:39

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered '2010'	System	10 Aug 2020 14:10:39

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered empty.	System	10 Aug 2020 14:10:39

US3262145

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered empty.	System	10 Aug 2020 14:10:39

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Dyslipidaemia, LLT: Dyslipidemia - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:16:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:16:22
Data point term sent to Coder	System	10 Aug 2020 14:11:32
User entered 'dyslipidemia'	Daisy Langarica (b) (4)	10 Aug 2020 14:10:57

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'un UNK 2010'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:57

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:57

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:57

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:57
	(b) (4)	

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:10:57

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'Jan 2010'	System	10 Aug 2020 14:10:57

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered '2010'	System	10 Aug 2020 14:10:57

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered empty.	System	10 Aug 2020 14:10:57

US3262145

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered empty.	System	10 Aug 2020 14:10:57

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:16:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:16:21
Data point term sent to Coder	System	10 Aug 2020 14:11:34
User entered 'anxiety'	Daisy Langarica (b) (4)	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'un UNK 2015'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'Jan 2015'	System	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered '2015'	System	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered empty.	System	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered empty.	System	10 Aug 2020 14:11:14

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
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)	10 Aug 2020 14:16:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Aug 2020 14:16:21
Data point term sent to Coder	System	10 Aug 2020 14:11:34
User entered 'type 2 diabetes'	Daisy Langarica (b) (4)	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'un UNK 2018'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'Jan 2018'	System	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered '2018'	System	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered empty.	System	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:18:25

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered empty.	System	10 Aug 2020 14:11:28

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:12:40

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '08 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:12:40
	(b) (4)	

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 14:12:47
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	10 Aug 2020 14:12:47
User entered '15:05' reason for change: Data Entry Error	Daisy Langarica (b) (4)	10 Aug 2020 14:12:47
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Aug 2020 14:12:40
User entered empty.	Daisy Langarica (b) (4)	10 Aug 2020 14:12:40
	(b) (4)	

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered '08 Aug 2020 15:05'	System	10 Aug 2020 14:12:47
User entered empty.	System	10 Aug 2020 14:12:40

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '60' in	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:12:40
DataPoint set to visible.	(b) (4) System	08 Aug 2020 22:37:36

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '232.0' lb	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:12:40
DataPoint set to visible.	(b) (4) System	08 Aug 2020 22:37:36

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
Amendment Manager: User entered '45.40413'	System	16 Sep 2020 23:49:12
User entered '45.4'	System	10 Aug 2020 14:12:40
DataPoint set to visible.	System	08 Aug 2020 22:37:36

US3262145

Folder: Screening

Form: Vital Signs

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[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'kg/m2'	System	10 Aug 2020 14:12:40
DataPoint set to visible.	System	08 Aug 2020 22:37:36

US3262145

Folder: Screening

Form: Vital Signs

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User closed query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:34:45
Query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' answered with 'Per CDM Screening and dosing (VID1) are done on the same day, "Not Done" is recorded.' (Site from DM).	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:24:48
User entered missing code ND - Not Done; reason for change Per Query Resolution	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:23:04
User opened query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:22:35
User closed query 'Per CDM: Response noted however, at Screening TEMP, PULSE, RESPIRATORY RATE, SYSTOLIC/DIASTOLIC BP should be entered as ND. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:22:35

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Query 'Per CDM: Response noted however, at Screening TEMP, PULSE, RESPIRATORY RATE, SYSTOLIC/DIASTOLIC BP should be entered as ND. Please review and update as appropriate. ' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	12 Nov 2020 15:55:27
User opened query 'Per CDM: Response noted however, at Screening TEMP, PULSE, RESPIRATORY RATE, SYSTOLIC/DIASTOLIC BP should be entered as ND. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 21:32:53
User closed query 'Per CDM: Per CCGs pages 15-16 ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM).		10 Nov 2020 21:32:53
Query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' answered with 'Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	25 Sep 2020 15:20:33
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be entered for TEMP, PULSE, RR, SBP, and DBP at screening and Kindly move this data to V1D1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:44:27
User entered '98.5' F	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:12:40

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Folder: Screening

Form: Vital Signs

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty; reason for change Data Entry Error	(b) (4) Alia Bober (b) (4)	03 Dec 2020 15:23:04
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:12:40

US3262145

Folder: Screening

Form: Vital Signs

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:12:40

US3262145

Folder: Screening

Form: Vital Signs

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User closed query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:34:57
Query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' answered with 'Per CDM Screening and dosing (VID1) are done on the same day, "Not Done" is recorded.' (Site from DM).	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:24:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:23:04
User opened query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:22:42
User entered '95'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:12:40

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'bpm'	System	10 Aug 2020 14:12:40

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User closed query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:35:21
Query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' answered with 'Per CDM Screening and dosing (VID1) are done on the same day, "Not Done" is recorded.' (Site from DM).	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:24:53
User entered missing code ND - Not Done; reason for change Per Query Resolution	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:23:04
User opened query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:22:48
User entered '14'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:12:40

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'breaths/min'	System	10 Aug 2020 14:12:40

US3262145

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User closed query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:35:23
Query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' answered with 'Per CDM Screening and dosing (VID1) are done on the same day, "Not Done" is recorded.' (Site from DM).	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:24:59
User entered missing code ND - Not Done; reason for change Per Query Resolution	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:23:04
User opened query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:22:54
User entered '130'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:12:40

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'mmHg'	System	10 Aug 2020 14:12:40

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User closed query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:35:26
Query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' answered with 'Per CDM Screening and dosing (VID1) are done on the same day, "Not Done" is recorded.' (Site from DM).	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:25:04
User entered missing code ND - Not Done; reason for change Per Query Resolution	Alia Bober (b) (4) (b) (4)	03 Dec 2020 15:23:04
User opened query 'Per CDM Re-Query: Per CCGs if Patient noted as screened and dosed same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at screening visit and Data to be filled at VID1 to avoid duplication. Please update accordingly. NOTE: Route is not required (blank)' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:23:00
User entered '80'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:12:40

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User entered 'mmHg'	System	10 Aug 2020 14:12:40

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:12:55

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
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)	07 Sep 2020 11:58:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	05 Sep 2020 23:09:56
User entered '08 Aug 2020'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:12:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:25

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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

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[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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

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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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

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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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

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[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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

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[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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

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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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

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[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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

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[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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:25

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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01
	(b) (4)	

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '1'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:25

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:25

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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:25

[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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:25

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 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

US3262145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '0'	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

US3262145

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:44
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	11 Aug 2020 00:01:01

US3262145

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	08 Aug 2020 22:37:49

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '08 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	08 Aug 2020 22:37:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

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[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 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4)	08 Aug 2020 22:37:49
	(b) (4)	

US3262145

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'VISIT1'	System	08 Aug 2020 22:37:49

US3262145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 22:20:23

US3262145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:10:02
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:10:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 22:20:23
User entered '143453' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 22:20:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 22:20:23

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Folder: Visit 1 Day 1

Form: Randomization

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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 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:13:18

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Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:13:18

US3262145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:13:18

US3262145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:25

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:13:18

US3262145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:13:18

US3262145

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:25

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	30 Nov 2020 13:28:39
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'No' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'No' (Site from DM).	Alia Bober (b) (4)	12 Nov 2020 15:55:05
User entered 'No (N)'	(b) (4)	
User entered 'No (N)'	Alia Bober (b) (4)	12 Nov 2020 15:54:58
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 18:06:47
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:04:12
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:40:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

US3262145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 05:52:37
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'ND. Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	25 Sep 2020 15:20:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	25 Sep 2020 15:20:49
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 18:16:34
User entered '232.0' lb	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 05:52:37
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'ND. Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	25 Sep 2020 15:20:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	25 Sep 2020 15:20:49
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 18:16:34
User entered '232.0' lb	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '08 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '15:05'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '08 Aug 2020 15:05'	System	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '98.5' F	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered empty.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '95'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'bpm'	System	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '14'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'breaths/min'	System	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '130'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '80'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User closed query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 05:52:37
Query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' answered with 'ND. Recorded at screening.' (Site from DM).	Alia Bober (b) (4) (b) (4)	25 Sep 2020 15:20:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Alia Bober (b) (4) (b) (4)	25 Sep 2020 15:20:49
User opened query 'Per CDM: Response noted, however per CCG's pages 15-16, Height and Weight should be entered as "ND". Please review and update else clarify ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 18:16:34
User entered '232.0' lb	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '08 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
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)	
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'CORRECT AS IS ' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 19:30:12
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'CORRECT AS IS ' (Site from System).	Daisy Langarica (b) (4)	11 Aug 2020 00:00:29
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	10 Aug 2020 14:17:24
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 14:17:24
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Aug 2020 14:17:24
User entered '15:52' reason for change: Data Entry Error	Daisy Langarica (b) (4)	10 Aug 2020 14:17:24
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	10 Aug 2020 14:17:04
	Daisy Langarica (b) (4)	10 Aug 2020 14:17:04
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '08 Aug 2020 15:52'	System	10 Aug 2020 14:17:24
User entered empty.	System	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '99.1' F	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered empty.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '92'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

US3262145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'bpm'	System	10 Aug 2020 14:17:04

US3262145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '16'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

US3262145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'breaths/min'	System	10 Aug 2020 14:17:04

US3262145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '129'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

US3262145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	10 Aug 2020 14:17:04

US3262145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '87'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:17:04

US3262145

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	10 Aug 2020 14:17:04

US3262145

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:06

US3262145

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '08 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:06
	(b) (4)	

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	08 Aug 2020 22:52:31

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	08 Aug 2020 22:52:31

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	08 Aug 2020 22:52:31
	(b) (4)	

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 22:52:31

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '08 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	08 Aug 2020 22:52:31

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '15:22'	(b) (4) Daisy Langarica (b) (4)	08 Aug 2020 22:52:31

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '08 Aug 2020 15:22'	System	08 Aug 2020 22:52:31

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langarica (b) (4)	08 Aug 2020 22:52:31

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'ONCE'	System	08 Aug 2020 22:52:31

US3262145

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 22:52:31

US3262145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:54

US3262145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '08 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:54
	(b) (4)	

US3262145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '15:16'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:54

US3262145

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '08 Aug 2020 15:16'	System	10 Aug 2020 14:14:54

US3262145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:18:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '08 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:37
	(b) (4)	

US3262145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:14:37

US3262145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:37

US3262145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '15:11'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:37

US3262145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '08 Aug 2020 15:11'	System	10 Aug 2020 14:14:37

US3262145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:14:37

US3262145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:37

US3262145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:37

US3262145

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered empty.	System	10 Aug 2020 14:14:37

US3262145

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	10 Aug 2020 14:14:10

US3262145

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '1'	System	10 Aug 2020 14:14:10

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:53:55', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1f51e798-687d-4c75-9f7d-c67b56b5b6d4'	System	08 Aug 2020 22:54:18
User entered 'Yes (Y)'	System	08 Aug 2020 22:54:18

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:02', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1f51e798-687d-4c75-9f7d-c67b56b5b6d4' User entered '99.0'	System	08 Aug 2020 22:54:18
	System	08 Aug 2020 22:54:18

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:08', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1f51e798-687d-4c75-9f7d-c67b56b5b6d4'	System	08 Aug 2020 22:54:18
User entered 'No (N)'	System	08 Aug 2020 22:54:18

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:15', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1f51e798-687d-4c75-9f7d-c67b56b5b6d4'	System	08 Aug 2020 22:54:18
User entered '08 Aug 2020 15:54'	System	08 Aug 2020 22:54:18

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Aug 2020 15:42'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Aug 2020 18:12'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:20:54', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cf738b1a-efc7-4dfa-884d-02e9ca7fe6cf'	System	09 Aug 2020 02:21:11
User entered 'Yes (Y)'	System	09 Aug 2020 02:21:11

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:21:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cf738b1a-efc7-4dfa-884d-02e9ca7fe6cf' User entered '97.2'	System	09 Aug 2020 02:21:11
	System	09 Aug 2020 02:21:11

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:21:03', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cf738b1a-efc7-4dfa-884d-02e9ca7fe6cf'	System	09 Aug 2020 02:21:11
User entered 'No (N)'	System	09 Aug 2020 02:21:11

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:21:07', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cf738b1a-efc7-4dfa-884d-02e9ca7fe6cf'	System	09 Aug 2020 02:21:11
User entered '08 Aug 2020 19:21'	System	09 Aug 2020 02:21:11

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Aug 2020 19:07'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 2'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:37:37', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ac825c9c-e6e8-4fc7-b49e-7a2abd6540d7'	System	09 Aug 2020 19:39:15
User entered 'Yes (Y)'	System	09 Aug 2020 19:39:15

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:39:05', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ac825c9c-e6e8-4fc7-b49e-7a2abd6540d7'	System	09 Aug 2020 19:39:15
User entered '97.4'	System	09 Aug 2020 19:39:15

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:39:08', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ac825c9c-e6e8-4fc7-b49e-7a2abd6540d7'	System	09 Aug 2020 19:39:15
User entered 'No (N)'	System	09 Aug 2020 19:39:15

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:39:13', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ac825c9c-e6e8-4fc7-b49e-7a2abd6540d7'	System	09 Aug 2020 19:39:15
User entered '09 Aug 2020 12:39'	System	09 Aug 2020 19:39:15

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 3'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:33:04', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ae25de7d-5a3b-482e-8f34-c27d6d3f9fdc'	System	10 Aug 2020 19:33:24
User entered 'Yes (Y)'	System	10 Aug 2020 19:33:24

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:33:13', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ae25de7d-5a3b-482e-8f34-c27d6d3f9fdc'	System	10 Aug 2020 19:33:24
User entered '98.0'	System	10 Aug 2020 19:33:24

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:33:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ae25de7d-5a3b-482e-8f34-c27d6d3f9fdc'	System	10 Aug 2020 19:33:24
User entered 'No (N)'	System	10 Aug 2020 19:33:24

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:33:20', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ae25de7d-5a3b-482e-8f34-c27d6d3f9fdc'	System	10 Aug 2020 19:33:24
User entered '10 Aug 2020 12:33'	System	10 Aug 2020 19:33:24

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 4'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:05:08', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '744e160b-54b9-40b0-8ebe-b1cc1e5ed1ac'	System	11 Aug 2020 19:05:23
User entered 'Yes (Y)'	System	11 Aug 2020 19:05:23

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:05:13', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '744e160b-54b9-40b0-8ebe-b1cc1e5ed1ac' User entered '97.5'	System	11 Aug 2020 19:05:23
	System	11 Aug 2020 19:05:23

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:05:15', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '744e160b-54b9-40b0-8ebe-b1cc1e5ed1ac'	System	11 Aug 2020 19:05:23
User entered 'No (N)'	System	11 Aug 2020 19:05:23

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:05:19', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '744e160b-54b9-40b0-8ebe-b1cc1e5ed1ac'	System	11 Aug 2020 19:05:23
User entered '11 Aug 2020 12:05'	System	11 Aug 2020 19:05:23

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 5'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:22:22', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4786563a-74d3-4e2a-86ea-5ea7a0d938f5'	System	12 Aug 2020 19:22:41
User entered 'Yes (Y)'	System	12 Aug 2020 19:22:41

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:22:32', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4786563a-74d3-4e2a-86ea-5ea7a0d938f5'	System	12 Aug 2020 19:22:41
User entered '96.9'	System	12 Aug 2020 19:22:41

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:22:34', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4786563a-74d3-4e2a-86ea-5ea7a0d938f5'	System	12 Aug 2020 19:22:41
User entered 'No (N)'	System	12 Aug 2020 19:22:41

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:22:37', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4786563a-74d3-4e2a-86ea-5ea7a0d938f5'	System	12 Aug 2020 19:22:41
User entered '12 Aug 2020 12:22'	System	12 Aug 2020 19:22:41

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 6'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:05:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'af9f2948-fd23-4dec-9ee0-1fc6ef49dbff'	System	13 Aug 2020 19:05:31
User entered 'Yes (Y)'	System	13 Aug 2020 19:05:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:05:22', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'af9f2948-fd23-4dec-9ee0-1fc6ef49dbff' User entered '97.3'	System	13 Aug 2020 19:05:31
	System	13 Aug 2020 19:05:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:05:25', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'af9f2948-fd23-4dec-9ee0-1fc6ef49dbff'	System	13 Aug 2020 19:05:31
User entered 'No (N)'	System	13 Aug 2020 19:05:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:05:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'af9f2948-fd23-4dec-9ee0-1fc6ef49dbff'	System	13 Aug 2020 19:05:31
User entered '13 Aug 2020 12:05'	System	13 Aug 2020 19:05:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 7'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:39:07', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '59463700-0943-4cb0-8e1a-276f6e41d7e3'	System	14 Aug 2020 19:39:22
User entered 'Yes (Y)'	System	14 Aug 2020 19:39:22

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:39:12', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '59463700-0943-4cb0-8e1a-276f6e41d7e3'	System	14 Aug 2020 19:39:22
User entered '97.4'	System	14 Aug 2020 19:39:22

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:39:15', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '59463700-0943-4cb0-8e1a-276f6e41d7e3'	System	14 Aug 2020 19:39:22
User entered 'No (N)'	System	14 Aug 2020 19:39:22

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:39:18', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '59463700-0943-4cb0-8e1a-276f6e41d7e3'	System	14 Aug 2020 19:39:22
User entered '14 Aug 2020 12:39'	System	14 Aug 2020 19:39:22

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:24', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'dddadfb0-3186-4db6-8d81-e3fd35bdba72'	System	08 Aug 2020 22:54:42
User entered 'None (1)'	System	08 Aug 2020 22:54:42

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:27', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'dddadfb0-3186-4db6-8d81-e3fd35bdba72'	System	08 Aug 2020 22:54:42
User entered 'No (N)'	System	08 Aug 2020 22:54:42

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:30', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'dddadfb0-3186-4db6-8d81-e3fd35bdba72'	System	08 Aug 2020 22:54:42
User entered 'No (N)'	System	08 Aug 2020 22:54:42

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:33', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'dddadfb0-3186-4db6-8d81-e3fd35bdba72'	System	08 Aug 2020 22:54:42
User entered 'None (1)'	System	08 Aug 2020 22:54:42

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:38', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'dddadfb0-3186-4db6-8d81-e3fd35bdba72'	System	08 Aug 2020 22:54:42
User entered '08 Aug 2020 15:54'	System	08 Aug 2020 22:54:42

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Aug 2020 15:42'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Aug 2020 18:12'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:21:39', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '851a0b6f-cee3-4e57-8268-e43119a2f282'	System	09 Aug 2020 02:22:11
User entered 'None (1)'	System	09 Aug 2020 02:22:11

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:21:52', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '851a0b6f-cee3-4e57-8268-e43119a2f282'	System	09 Aug 2020 02:22:11
User entered 'No (N)'	System	09 Aug 2020 02:22:11

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:21:55', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '851a0b6f-cee3-4e57-8268-e43119a2f282'	System	09 Aug 2020 02:22:11
User entered 'No (N)'	System	09 Aug 2020 02:22:11

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:22:02', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '851a0b6f-cee3-4e57-8268-e43119a2f282'	System	09 Aug 2020 02:22:11
User entered 'None (1)'	System	09 Aug 2020 02:22:11

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:22:06', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '851a0b6f-cee3-4e57-8268-e43119a2f282'	System	09 Aug 2020 02:22:11
User entered '08 Aug 2020 19:22'	System	09 Aug 2020 02:22:11

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Aug 2020 19:07'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 2'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:39:20', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '205a80fa-d80a-4de7-a398-bc684432c12a'	System	09 Aug 2020 19:40:25
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 19:40:25

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:39:25', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '205a80fa-d80a-4de7-a398-bc684432c12a'	System	09 Aug 2020 19:40:25
User entered 'No (N)'	System	09 Aug 2020 19:40:25

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:39:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '205a80fa-d80a-4de7-a398-bc684432c12a'	System	09 Aug 2020 19:40:25
User entered 'Yes (Y)'	System	09 Aug 2020 19:40:25

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:10', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '205a80fa-d80a-4de7-a398-bc684432c12a'	System	09 Aug 2020 19:40:25
User entered '16'	System	09 Aug 2020 19:40:25

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:14', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '205a80fa-d80a-4de7-a398-bc684432c12a'	System	09 Aug 2020 19:40:25
User entered 'None (1)'	System	09 Aug 2020 19:40:25

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:22', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '205a80fa-d80a-4de7-a398-bc684432c12a'	System	09 Aug 2020 19:40:25
User entered '09 Aug 2020 12:40'	System	09 Aug 2020 19:40:25

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 3'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:34:22', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2667bdb5-1f1d-4629-9582-288c42acb3ed'	System	10 Aug 2020 19:34:47
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 19:34:47

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:34:25', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2667bdb5-1f1d-4629-9582-288c42acb3ed'	System	10 Aug 2020 19:34:47
User entered 'No (N)'	System	10 Aug 2020 19:34:47

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:34:28', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2667bdb5-1f1d-4629-9582-288c42acb3ed'	System	10 Aug 2020 19:34:47
User entered 'Yes (Y)'	System	10 Aug 2020 19:34:47

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:34:33', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2667bdb5-1f1d-4629-9582-288c42acb3ed' User entered '15'	System	10 Aug 2020 19:34:47
	System	10 Aug 2020 19:34:47

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:34:39', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2667bdb5-1f1d-4629-9582-288c42acb3ed'	System	10 Aug 2020 19:34:47
User entered 'None (1)'	System	10 Aug 2020 19:34:47

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:34:44', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2667bdb5-1f1d-4629-9582-288c42acb3ed' User entered '10 Aug 2020 12:34'	System	10 Aug 2020 19:34:47
	System	10 Aug 2020 19:34:47

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 4'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:05:28', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1b9cf640-8dfa-4bf2-a1f3-abf1f2df9a43'	System	11 Aug 2020 19:06:20
User entered 'None (1)'	System	11 Aug 2020 19:06:20

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:05:31', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1b9cf640-8dfa-4bf2-a1f3-abf1f2df9a43'	System	11 Aug 2020 19:06:20
User entered 'No (N)'	System	11 Aug 2020 19:06:20

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:01', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1b9cf640-8dfa-4bf2-a1f3-abf1f2df9a43'	System	11 Aug 2020 19:06:20
User entered 'Yes (Y)'	System	11 Aug 2020 19:06:20

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:07', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1b9cf640-8dfa-4bf2-a1f3-abf1f2df9a43'	System	11 Aug 2020 19:06:20
User entered '15'	System	11 Aug 2020 19:06:20

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:12', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1b9cf640-8dfa-4bf2-a1f3-abf1f2df9a43'	System	11 Aug 2020 19:06:20
User entered 'None (1)'	System	11 Aug 2020 19:06:20

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:18', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1b9cf640-8dfa-4bf2-a1f3-abf1f2df9a43'	System	11 Aug 2020 19:06:20
User entered '11 Aug 2020 12:06'	System	11 Aug 2020 19:06:20

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 5'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:22:44', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7cb755a7-23e6-4279-802c-a5344e516a10'	System	12 Aug 2020 19:23:09
User entered 'None (1)'	System	12 Aug 2020 19:23:09

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:22:46', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7cb755a7-23e6-4279-802c-a5344e516a10'	System	12 Aug 2020 19:23:09
User entered 'No (N)'	System	12 Aug 2020 19:23:09

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:22:50', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7cb755a7-23e6-4279-802c-a5344e516a10'	System	12 Aug 2020 19:23:09
User entered 'Yes (Y)'	System	12 Aug 2020 19:23:09

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:22:53', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7cb755a7-23e6-4279-802c-a5344e516a10'	System	12 Aug 2020 19:23:09
User entered '10'	System	12 Aug 2020 19:23:09

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:22:56', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7cb755a7-23e6-4279-802c-a5344e516a10'	System	12 Aug 2020 19:23:09
User entered 'None (1)'	System	12 Aug 2020 19:23:09

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:23:03', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7cb755a7-23e6-4279-802c-a5344e516a10'	System	12 Aug 2020 19:23:09
User entered '12 Aug 2020 12:23'	System	12 Aug 2020 19:23:09

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 6'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:05:47', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '929d70e4-f69f-4d37-a397-46f83118fdfe'	System	13 Aug 2020 19:06:23
User entered 'None (1)'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:05:49', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '929d70e4-f69f-4d37-a397-46f83118fdfe'	System	13 Aug 2020 19:06:23
User entered 'No (N)'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:05', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '929d70e4-f69f-4d37-a397-46f83118fdfe'	System	13 Aug 2020 19:06:23
User entered 'Yes (Y)'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:08', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '929d70e4-f69f-4d37-a397-46f83118fdfe'	System	13 Aug 2020 19:06:23
User entered '5'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:11', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '929d70e4-f69f-4d37-a397-46f83118fdfe'	System	13 Aug 2020 19:06:23
User entered 'None (1)'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:18', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '929d70e4-f69f-4d37-a397-46f83118fdfe'	System	13 Aug 2020 19:06:23
User entered '13 Aug 2020 12:06'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 7'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:39:25', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '837883db-04f7-4821-9ea7-d5c7331df303'	System	14 Aug 2020 19:40:12
User entered 'None (1)'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:39:53', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '837883db-04f7-4821-9ea7-d5c7331df303'	System	14 Aug 2020 19:40:12
User entered 'No (N)'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:39:56', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '837883db-04f7-4821-9ea7-d5c7331df303'	System	14 Aug 2020 19:40:12
User entered 'Yes (Y)'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:39:59', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '837883db-04f7-4821-9ea7-d5c7331df303'	System	14 Aug 2020 19:40:12
User entered '12'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:02', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '837883db-04f7-4821-9ea7-d5c7331df303'	System	14 Aug 2020 19:40:12
User entered 'None (1)'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:10', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '837883db-04f7-4821-9ea7-d5c7331df303'	System	14 Aug 2020 19:40:12
User entered '14 Aug 2020 12:40'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:43', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cc46e41c-3b3a-4cb3-a1b6-a183bae0e71a'	System	08 Aug 2020 22:55:04
User entered 'None (0)'	System	08 Aug 2020 22:55:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:46', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cc46e41c-3b3a-4cb3-a1b6-a183bae0e71a'	System	08 Aug 2020 22:55:04
User entered 'None (0)'	System	08 Aug 2020 22:55:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:48', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cc46e41c-3b3a-4cb3-a1b6-a183bae0e71a'	System	08 Aug 2020 22:55:04
User entered 'None (0)'	System	08 Aug 2020 22:55:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:51', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cc46e41c-3b3a-4cb3-a1b6-a183bae0e71a'	System	08 Aug 2020 22:55:04
User entered 'None (0)'	System	08 Aug 2020 22:55:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:54', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cc46e41c-3b3a-4cb3-a1b6-a183bae0e71a'	System	08 Aug 2020 22:55:04
User entered 'None (0)'	System	08 Aug 2020 22:55:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:56', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cc46e41c-3b3a-4cb3-a1b6-a183bae0e71a'	System	08 Aug 2020 22:55:04
User entered 'None (0)'	System	08 Aug 2020 22:55:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:54:59', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cc46e41c-3b3a-4cb3-a1b6-a183bae0e71a'	System	08 Aug 2020 22:55:04
User entered 'No (N)'	System	08 Aug 2020 22:55:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T15:55:02', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'cc46e41c-3b3a-4cb3-a1b6-a183bae0e71a'	System	08 Aug 2020 22:55:04
User entered '08 Aug 2020 15:55'	System	08 Aug 2020 22:55:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Aug 2020 15:42'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Aug 2020 18:12'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:22:11', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ff798209-4f13-451b-8e46-d3dd068a2610'	System	09 Aug 2020 02:23:02
User entered 'None (0)'	System	09 Aug 2020 02:23:02

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:22:19', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ff798209-4f13-451b-8e46-d3dd068a2610'	System	09 Aug 2020 02:23:02
User entered 'No interference with activity (1)'	System	09 Aug 2020 02:23:02

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:22:26', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ff798209-4f13-451b-8e46-d3dd068a2610'	System	09 Aug 2020 02:23:02
User entered 'No interference with activity (1)'	System	09 Aug 2020 02:23:02

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:22:31', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ff798209-4f13-451b-8e46-d3dd068a2610'	System	09 Aug 2020 02:23:02
User entered 'None (0)'	System	09 Aug 2020 02:23:02

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:22:41', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ff798209-4f13-451b-8e46-d3dd068a2610'	System	09 Aug 2020 02:23:02
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Aug 2020 02:23:02

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:22:43', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ff798209-4f13-451b-8e46-d3dd068a2610'	System	09 Aug 2020 02:23:02
User entered 'None (0)'	System	09 Aug 2020 02:23:02

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:22:49', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ff798209-4f13-451b-8e46-d3dd068a2610'	System	09 Aug 2020 02:23:02
User entered 'No (N)'	System	09 Aug 2020 02:23:02

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-08T19:23:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ff798209-4f13-451b-8e46-d3dd068a2610'	System	09 Aug 2020 02:23:02
User entered '08 Aug 2020 19:23'	System	09 Aug 2020 02:23:02

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Aug 2020 19:07'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 2'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:28', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '201801d8-e085-4a47-b897-460f0742badd'	System	09 Aug 2020 19:41:04
User entered 'None (0)'	System	09 Aug 2020 19:41:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:33', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '201801d8-e085-4a47-b897-460f0742badd'	System	09 Aug 2020 19:41:04
User entered 'No interference with activity (1)'	System	09 Aug 2020 19:41:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:38', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '201801d8-e085-4a47-b897-460f0742badd'	System	09 Aug 2020 19:41:04
User entered 'None (0)'	System	09 Aug 2020 19:41:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:42', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '201801d8-e085-4a47-b897-460f0742badd'	System	09 Aug 2020 19:41:04
User entered 'None (0)'	System	09 Aug 2020 19:41:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:45', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '201801d8-e085-4a47-b897-460f0742badd'	System	09 Aug 2020 19:41:04
User entered 'None (0)'	System	09 Aug 2020 19:41:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:48', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '201801d8-e085-4a47-b897-460f0742badd'	System	09 Aug 2020 19:41:04
User entered 'None (0)'	System	09 Aug 2020 19:41:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:40:53', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '201801d8-e085-4a47-b897-460f0742badd'	System	09 Aug 2020 19:41:04
User entered 'No (N)'	System	09 Aug 2020 19:41:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-09T12:41:01', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '201801d8-e085-4a47-b897-460f0742badd'	System	09 Aug 2020 19:41:04
User entered '09 Aug 2020 12:41'	System	09 Aug 2020 19:41:04

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 3'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:34:57', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4df063ad-7531-47b3-b5e4-4bcb70586505'	System	10 Aug 2020 19:35:48
User entered 'No interference with activity (1)'	System	10 Aug 2020 19:35:48

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:35:03', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4df063ad-7531-47b3-b5e4-4bcb70586505'	System	10 Aug 2020 19:35:48
User entered 'Some interference with activity (2)'	System	10 Aug 2020 19:35:48

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:35:08', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4df063ad-7531-47b3-b5e4-4bcb70586505'	System	10 Aug 2020 19:35:48
User entered 'Some interference with activity (2)'	System	10 Aug 2020 19:35:48

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:35:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4df063ad-7531-47b3-b5e4-4bcb70586505'	System	10 Aug 2020 19:35:48
User entered 'None (0)'	System	10 Aug 2020 19:35:48

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:35:22', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4df063ad-7531-47b3-b5e4-4bcb70586505'	System	10 Aug 2020 19:35:48
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Aug 2020 19:35:48

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:35:25', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4df063ad-7531-47b3-b5e4-4bcb70586505'	System	10 Aug 2020 19:35:48
User entered 'None (0)'	System	10 Aug 2020 19:35:48

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:35:32', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4df063ad-7531-47b3-b5e4-4bcb70586505'	System	10 Aug 2020 19:35:48
User entered 'No (N)'	System	10 Aug 2020 19:35:48

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-10T12:35:45', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4df063ad-7531-47b3-b5e4-4bcb70586505'	System	10 Aug 2020 19:35:48
User entered '10 Aug 2020 12:35'	System	10 Aug 2020 19:35:48

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 4'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:26', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '87b32fdd-e666-482b-93dc-488bc2a2d09b'	System	11 Aug 2020 19:07:11
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:07:11

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '87b32fdd-e666-482b-93dc-488bc2a2d09b'	System	11 Aug 2020 19:07:11
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:07:11

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:32', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '87b32fdd-e666-482b-93dc-488bc2a2d09b'	System	11 Aug 2020 19:07:11
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:07:11

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:39', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '87b32fdd-e666-482b-93dc-488bc2a2d09b'	System	11 Aug 2020 19:07:11
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:07:11

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:42', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '87b32fdd-e666-482b-93dc-488bc2a2d09b'	System	11 Aug 2020 19:07:11
User entered 'None (0)'	System	11 Aug 2020 19:07:11

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:44', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '87b32fdd-e666-482b-93dc-488bc2a2d09b'	System	11 Aug 2020 19:07:11
User entered 'None (0)'	System	11 Aug 2020 19:07:11

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:52', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '87b32fdd-e666-482b-93dc-488bc2a2d09b'	System	11 Aug 2020 19:07:11
User entered 'No (N)'	System	11 Aug 2020 19:07:11

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-11T12:06:59', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '87b32fdd-e666-482b-93dc-488bc2a2d09b'	System	11 Aug 2020 19:07:11
User entered '11 Aug 2020 12:06'	System	11 Aug 2020 19:07:11

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 5'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:23:07', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5b3b91c5-df7b-413d-9509-10e5466dbcba'	System	12 Aug 2020 19:23:33
User entered 'None (0)'	System	12 Aug 2020 19:23:33

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:23:09', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5b3b91c5-df7b-413d-9509-10e5466dbcba'	System	12 Aug 2020 19:23:33
User entered 'None (0)'	System	12 Aug 2020 19:23:33

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:23:11', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5b3b91c5-df7b-413d-9509-10e5466dbcba'	System	12 Aug 2020 19:23:33
User entered 'None (0)'	System	12 Aug 2020 19:23:33

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:23:14', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5b3b91c5-df7b-413d-9509-10e5466dbcba'	System	12 Aug 2020 19:23:33
User entered 'None (0)'	System	12 Aug 2020 19:23:33

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:23:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5b3b91c5-df7b-413d-9509-10e5466dbcba'	System	12 Aug 2020 19:23:33
User entered 'None (0)'	System	12 Aug 2020 19:23:33

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:23:18', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5b3b91c5-df7b-413d-9509-10e5466dbcba'	System	12 Aug 2020 19:23:33
User entered 'None (0)'	System	12 Aug 2020 19:23:33

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:23:23', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5b3b91c5-df7b-413d-9509-10e5466dbcba'	System	12 Aug 2020 19:23:33
User entered 'No (N)'	System	12 Aug 2020 19:23:33

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-12T12:23:30', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5b3b91c5-df7b-413d-9509-10e5466dbcba'	System	12 Aug 2020 19:23:33
User entered '12 Aug 2020 12:23'	System	12 Aug 2020 19:23:33

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 6'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:22', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '35d7d80c-3c23-4b92-a54b-9e348b83178e'	System	13 Aug 2020 19:06:46
User entered 'None (0)'	System	13 Aug 2020 19:06:46

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:24', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '35d7d80c-3c23-4b92-a54b-9e348b83178e'	System	13 Aug 2020 19:06:46
User entered 'None (0)'	System	13 Aug 2020 19:06:46

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:27', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '35d7d80c-3c23-4b92-a54b-9e348b83178e'	System	13 Aug 2020 19:06:46
User entered 'None (0)'	System	13 Aug 2020 19:06:46

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '35d7d80c-3c23-4b92-a54b-9e348b83178e'	System	13 Aug 2020 19:06:46
User entered 'None (0)'	System	13 Aug 2020 19:06:46

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:31', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '35d7d80c-3c23-4b92-a54b-9e348b83178e'	System	13 Aug 2020 19:06:46
User entered 'None (0)'	System	13 Aug 2020 19:06:46

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:33', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '35d7d80c-3c23-4b92-a54b-9e348b83178e'	System	13 Aug 2020 19:06:46
User entered 'None (0)'	System	13 Aug 2020 19:06:46

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:36', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '35d7d80c-3c23-4b92-a54b-9e348b83178e'	System	13 Aug 2020 19:06:46
User entered 'No (N)'	System	13 Aug 2020 19:06:46

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-13T12:06:43', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '35d7d80c-3c23-4b92-a54b-9e348b83178e'	System	13 Aug 2020 19:06:46
User entered '13 Aug 2020 12:06'	System	13 Aug 2020 19:06:46

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 7'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:14', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '75a24575-cbda-4042-9298-9e78d2967678'	System	14 Aug 2020 19:40:34
User entered 'None (0)'	System	14 Aug 2020 19:40:34

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '75a24575-cbda-4042-9298-9e78d2967678'	System	14 Aug 2020 19:40:34
User entered 'None (0)'	System	14 Aug 2020 19:40:34

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:17', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '75a24575-cbda-4042-9298-9e78d2967678'	System	14 Aug 2020 19:40:34
User entered 'None (0)'	System	14 Aug 2020 19:40:34

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:19', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '75a24575-cbda-4042-9298-9e78d2967678'	System	14 Aug 2020 19:40:34
User entered 'None (0)'	System	14 Aug 2020 19:40:34

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:21', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '75a24575-cbda-4042-9298-9e78d2967678'	System	14 Aug 2020 19:40:34
User entered 'None (0)'	System	14 Aug 2020 19:40:34

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:24', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '75a24575-cbda-4042-9298-9e78d2967678'	System	14 Aug 2020 19:40:34
User entered 'None (0)'	System	14 Aug 2020 19:40:34

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:27', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '75a24575-cbda-4042-9298-9e78d2967678'	System	14 Aug 2020 19:40:34
User entered 'No (N)'	System	14 Aug 2020 19:40:34

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-14T12:40:32', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '75a24575-cbda-4042-9298-9e78d2967678'	System	14 Aug 2020 19:40:34
User entered '14 Aug 2020 12:40'	System	14 Aug 2020 19:40:34

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	13 Aug 2020 19:06:23
User entered 'Day 8'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-15T14:31:24', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b08582f4-3139-4c39-85c7-513d33e6b639'	System	15 Aug 2020 21:31:35
User entered 'Yes (Y)'	System	15 Aug 2020 21:31:35

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-15T14:31:28', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b08582f4-3139-4c39-85c7-513d33e6b639'	System	15 Aug 2020 21:31:35
User entered '5'	System	15 Aug 2020 21:31:35

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-15T14:31:32', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b08582f4-3139-4c39-85c7-513d33e6b639'	System	15 Aug 2020 21:31:35
User entered '15 Aug 2020 14:31'	System	15 Aug 2020 21:31:35

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	14 Aug 2020 19:40:12
User entered 'Day 9'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-16T14:07:01', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '60c2b8be-ff3e-4dd2-a0b1-27f67c7090c1'	System	16 Aug 2020 21:07:07
User entered 'No (N)'	System	16 Aug 2020 21:07:07

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-16T14:07:04', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '60c2b8be-ff3e-4dd2-a0b1-27f67c7090c1' User entered '16 Aug 2020 14:07'	System	16 Aug 2020 21:07:07
	System	16 Aug 2020 21:07:07

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	13 Aug 2020 19:06:23
User entered 'Day 8'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-15T14:31:40', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'adc94976-87bc-4b35-a630-ff2d12f17ca7'	System	15 Aug 2020 21:31:46
User entered 'No (N)'	System	15 Aug 2020 21:31:46

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-15T14:31:42', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'adc94976-87bc-4b35-a630-ff2d12f17ca7'	System	15 Aug 2020 21:31:46
User entered '15 Aug 2020 14:31'	System	15 Aug 2020 21:31:46

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 19:06:23

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	14 Aug 2020 19:40:12
User entered 'Day 9'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-16T14:07:08', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'a37908b5-e71e-46da-91dd-b6ffef5420fc'	System	16 Aug 2020 21:07:16
User entered 'No (N)'	System	16 Aug 2020 21:07:16

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-08-16T14:07:11', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'a37908b5-e71e-46da-91dd-b6ffef5420fc' User entered '16 Aug 2020 14:07'	System	16 Aug 2020 21:07:16
	System	16 Aug 2020 21:07:16

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:40:12

US3262145

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:40:12

US3262145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 19:26:39

US3262145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 19:26:39

US3262145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 19:26:39

US3262145

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 19:26:39

US3262145

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 19:26:45

US3262145

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'I'	System	17 Aug 2020 19:26:45

US3262145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:42

US3262145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '22 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:42

US3262145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:42

US3262145

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:42

US3262145

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 01:49:49

US3262145

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User entered '1'	System	30 Aug 2020 01:49:49

US3262145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 01:50:11

US3262145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 01:50:11

US3262145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 01:50:11

US3262145

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 01:50:11

US3262145

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 01:50:17

US3262145

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User entered '1'	System	30 Aug 2020 01:50:17

US3262145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:09:56
	(b) (4)	

US3262145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:09:56
	(b) (4)	

US3262145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[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 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:09:56
	(b) (4)	

US3262145

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'VISIT2'	System	05 Sep 2020 23:09:56

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04
	(b) (4)	

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '15:05'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '05 Sep 2020 15:05'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '99.1' F	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '87'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'bpm'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '16'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'breaths/min'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '124'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '82'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04
	(b) (4)	

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '15:53'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '05 Sep 2020 15:53'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '98.3' F	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '83'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'bpm'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '16'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'breaths/min'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '112'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '78'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	05 Sep 2020 23:12:04

US3262145

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:05

US3262145

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:05

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 22:53:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 22:53:58
	(b) (4)	

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 22:53:58
	(b) (4)	

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'MRNA-1273 OR PLACEBO'	System	05 Sep 2020 22:53:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 22:53:58
	(b) (4)	

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	12 Feb 2021 22:52:35
User entered '15:23' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 22:59:51
User entered '15:53'	Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 22:53:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '05 Sep 2020 15:23'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 15:53'	System	05 Sep 2020 22:53:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 22:53:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'ONCE'	System	05 Sep 2020 22:53:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'INTRAMUSCULAR'	System	05 Sep 2020 22:53:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:45

US3262145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:45
	(b) (4)	

US3262145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '15:10'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:45

US3262145

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '05 Sep 2020 15:10'	System	05 Sep 2020 23:10:45

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:18:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '05 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 23:10:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '15:07'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '05 Sep 2020 15:07'	System	05 Sep 2020 23:10:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Daisy Langarica (b) (4) (b) (4)	05 Sep 2020 23:10:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 23:10:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered empty.	System	05 Sep 2020 23:10:58

US3262145

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Sep 2020 22:54:17

US3262145

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '1'	System	05 Sep 2020 22:54:17

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2d1deb2a-5783-42e6-8c40-6a695f3a5e7f'	System	05 Sep 2020 23:00:36
User entered 'Yes (Y)'	System	05 Sep 2020 23:00:36

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:24', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2d1deb2a-5783-42e6-8c40-6a695f3a5e7f' User entered '98.3'	System	05 Sep 2020 23:00:36
	System	05 Sep 2020 23:00:36

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:26', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2d1deb2a-5783-42e6-8c40-6a695f3a5e7f'	System	05 Sep 2020 23:00:36
User entered 'No (N)'	System	05 Sep 2020 23:00:36

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2d1deb2a-5783-42e6-8c40-6a695f3a5e7f'	System	05 Sep 2020 23:00:36
User entered '05 Sep 2020 16:00'	System	05 Sep 2020 23:00:36

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '05 Sep 2020 15:43'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 16:13'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '05 Sep 2020 18:13'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 18:43'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:14', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9252b60d-d51d-4b3f-9444-ab2a1028e58d'	System	06 Sep 2020 04:28:32
User entered 'Yes (Y)'	System	06 Sep 2020 04:28:32

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:22', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9252b60d-d51d-4b3f-9444-ab2a1028e58d'	System	06 Sep 2020 04:28:32
User entered '98.0'	System	06 Sep 2020 04:28:32

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:25', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9252b60d-d51d-4b3f-9444-ab2a1028e58d'	System	06 Sep 2020 04:28:32
User entered 'No (N)'	System	06 Sep 2020 04:28:32

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:27', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9252b60d-d51d-4b3f-9444-ab2a1028e58d'	System	06 Sep 2020 04:28:32
User entered '05 Sep 2020 21:28'	System	06 Sep 2020 04:28:32

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '05 Sep 2020 19:08'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 19:38'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 2'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:06:14', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1112ecae-2ac8-4252-a6aa-24a96a710f41'	System	06 Sep 2020 19:06:32
User entered 'Yes (Y)'	System	06 Sep 2020 19:06:32

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:06:19', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1112ecae-2ac8-4252-a6aa-24a96a710f41'	System	06 Sep 2020 19:06:32
User entered '96.1'	System	06 Sep 2020 19:06:32

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:06:22', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1112ecae-2ac8-4252-a6aa-24a96a710f41'	System	06 Sep 2020 19:06:32
User entered 'No (N)'	System	06 Sep 2020 19:06:32

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:06:26', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1112ecae-2ac8-4252-a6aa-24a96a710f41'	System	06 Sep 2020 19:06:32
User entered '06 Sep 2020 12:06'	System	06 Sep 2020 19:06:32

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 3'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:50:33', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '39138a1d-a1b2-4717-af38-501d0a85a5b0'	System	07 Sep 2020 19:50:50
User entered 'Yes (Y)'	System	07 Sep 2020 19:50:50

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:50:39', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '39138a1d-a1b2-4717-af38-501d0a85a5b0'	System	07 Sep 2020 19:50:50
User entered '96.9'	System	07 Sep 2020 19:50:50

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:50:42', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '39138a1d-a1b2-4717-af38-501d0a85a5b0'	System	07 Sep 2020 19:50:50
User entered 'No (N)'	System	07 Sep 2020 19:50:50

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:50:45', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '39138a1d-a1b2-4717-af38-501d0a85a5b0'	System	07 Sep 2020 19:50:50
User entered '07 Sep 2020 12:50'	System	07 Sep 2020 19:50:50

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 4'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:05:01', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1f7cce8d-655b-463f-8246-365789a1916c'	System	08 Sep 2020 19:05:16
User entered 'Yes (Y)'	System	08 Sep 2020 19:05:16

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:05:07', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1f7cce8d-655b-463f-8246-365789a1916c'	System	08 Sep 2020 19:05:16
User entered '97.0'	System	08 Sep 2020 19:05:16

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:05:09', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1f7cce8d-655b-463f-8246-365789a1916c'	System	08 Sep 2020 19:05:16
User entered 'No (N)'	System	08 Sep 2020 19:05:16

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:05:12', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1f7cce8d-655b-463f-8246-365789a1916c'	System	08 Sep 2020 19:05:16
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 19:05:16

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 5'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:00:56', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ce58f57c-cab3-4214-b4b9-2737aa3c15c8'	System	09 Sep 2020 20:01:16
User entered 'Yes (Y)'	System	09 Sep 2020 20:01:16

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:01', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ce58f57c-cab3-4214-b4b9-2737aa3c15c8'	System	09 Sep 2020 20:01:16
User entered '97.1'	System	09 Sep 2020 20:01:16

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:07', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ce58f57c-cab3-4214-b4b9-2737aa3c15c8'	System	09 Sep 2020 20:01:16
User entered 'No (N)'	System	09 Sep 2020 20:01:16

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:13', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ce58f57c-cab3-4214-b4b9-2737aa3c15c8'	System	09 Sep 2020 20:01:16
User entered '09 Sep 2020 13:01'	System	09 Sep 2020 20:01:16

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 6'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:48:38', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'f1ebc55b-a8eb-45a1-a907-2c3f22934d9a'	System	10 Sep 2020 19:48:52
User entered 'Yes (Y)'	System	10 Sep 2020 19:48:52

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:48:43', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'f1ebc55b-a8eb-45a1-a907-2c3f22934d9a'	System	10 Sep 2020 19:48:52
User entered '97.0'	System	10 Sep 2020 19:48:52

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:48:46', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'f1ebc55b-a8eb-45a1-a907-2c3f22934d9a'	System	10 Sep 2020 19:48:52
User entered 'No (N)'	System	10 Sep 2020 19:48:52

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:48:48', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'f1ebc55b-a8eb-45a1-a907-2c3f22934d9a'	System	10 Sep 2020 19:48:52
User entered '10 Sep 2020 12:48'	System	10 Sep 2020 19:48:52

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 7'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:03:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3c35e79c-8fa3-49cc-b097-63ddc4f95d9c'	System	11 Sep 2020 19:03:50
User entered 'Yes (Y)'	System	11 Sep 2020 19:03:50

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:03:34', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3c35e79c-8fa3-49cc-b097-63ddc4f95d9c'	System	11 Sep 2020 19:03:50
User entered '97.1'	System	11 Sep 2020 19:03:50

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:03:36', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3c35e79c-8fa3-49cc-b097-63ddc4f95d9c'	System	11 Sep 2020 19:03:50
User entered 'No (N)'	System	11 Sep 2020 19:03:50

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:03:38', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3c35e79c-8fa3-49cc-b097-63ddc4f95d9c'	System	11 Sep 2020 19:03:50
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 19:03:50

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:36', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'a09d65c9-2e2c-4590-8284-0170f6f492a1'	System	05 Sep 2020 23:00:53
User entered 'None (1)'	System	05 Sep 2020 23:00:53

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:39', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'a09d65c9-2e2c-4590-8284-0170f6f492a1'	System	05 Sep 2020 23:00:53
User entered 'No (N)'	System	05 Sep 2020 23:00:53

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:41', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'a09d65c9-2e2c-4590-8284-0170f6f492a1'	System	05 Sep 2020 23:00:53
User entered 'No (N)'	System	05 Sep 2020 23:00:53

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:44', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'a09d65c9-2e2c-4590-8284-0170f6f492a1'	System	05 Sep 2020 23:00:53
User entered 'None (1)'	System	05 Sep 2020 23:00:53

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:47', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'a09d65c9-2e2c-4590-8284-0170f6f492a1'	System	05 Sep 2020 23:00:53
User entered '05 Sep 2020 16:00'	System	05 Sep 2020 23:00:53

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '05 Sep 2020 15:43'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 16:13'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '05 Sep 2020 18:13'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 18:43'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:34', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '8d1024ab-8aea-4dfb-aff3-079432265a3d'	System	06 Sep 2020 04:28:48
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 04:28:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:36', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '8d1024ab-8aea-4dfb-aff3-079432265a3d'	System	06 Sep 2020 04:28:48
User entered 'No (N)'	System	06 Sep 2020 04:28:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:38', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '8d1024ab-8aea-4dfb-aff3-079432265a3d'	System	06 Sep 2020 04:28:48
User entered 'No (N)'	System	06 Sep 2020 04:28:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:41', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '8d1024ab-8aea-4dfb-aff3-079432265a3d'	System	06 Sep 2020 04:28:48
User entered 'None (1)'	System	06 Sep 2020 04:28:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:43', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '8d1024ab-8aea-4dfb-aff3-079432265a3d'	System	06 Sep 2020 04:28:48
User entered '05 Sep 2020 21:28'	System	06 Sep 2020 04:28:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '05 Sep 2020 19:08'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 19:38'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 2'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:06:59', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b2040560-1065-4e67-a0b2-d85e4a79a0c1'	System	06 Sep 2020 19:07:21
User entered 'None (1)'	System	06 Sep 2020 19:07:21

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:02', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b2040560-1065-4e67-a0b2-d85e4a79a0c1'	System	06 Sep 2020 19:07:21
User entered 'No (N)'	System	06 Sep 2020 19:07:21

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:05', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b2040560-1065-4e67-a0b2-d85e4a79a0c1'	System	06 Sep 2020 19:07:21
User entered 'Yes (Y)'	System	06 Sep 2020 19:07:21

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:10', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b2040560-1065-4e67-a0b2-d85e4a79a0c1' User entered '15'	System	06 Sep 2020 19:07:21
	System	06 Sep 2020 19:07:21

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:13', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b2040560-1065-4e67-a0b2-d85e4a79a0c1'	System	06 Sep 2020 19:07:21
User entered 'None (1)'	System	06 Sep 2020 19:07:21

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b2040560-1065-4e67-a0b2-d85e4a79a0c1'	System	06 Sep 2020 19:07:21
User entered '06 Sep 2020 12:07'	System	06 Sep 2020 19:07:21

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 3'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:50:50', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1d05c0fd-000f-4b2b-873f-52aa7ceb3485'	System	07 Sep 2020 19:51:07
User entered 'None (1)'	System	07 Sep 2020 19:51:07

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:50:52', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1d05c0fd-000f-4b2b-873f-52aa7ceb3485'	System	07 Sep 2020 19:51:07
User entered 'No (N)'	System	07 Sep 2020 19:51:07

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:50:54', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1d05c0fd-000f-4b2b-873f-52aa7ceb3485'	System	07 Sep 2020 19:51:07
User entered 'Yes (Y)'	System	07 Sep 2020 19:51:07

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:50:58', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1d05c0fd-000f-4b2b-873f-52aa7ceb3485'	System	07 Sep 2020 19:51:07
User entered '12'	System	07 Sep 2020 19:51:07

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:01', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1d05c0fd-000f-4b2b-873f-52aa7ceb3485'	System	07 Sep 2020 19:51:07
User entered 'None (1)'	System	07 Sep 2020 19:51:07

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:03', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1d05c0fd-000f-4b2b-873f-52aa7ceb3485'	System	07 Sep 2020 19:51:07
User entered '07 Sep 2020 12:51'	System	07 Sep 2020 19:51:07

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 4'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:12', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9f854a9f-409f-422a-85e7-9f2ca231e497'	System	08 Sep 2020 19:04:48
User entered 'None (1)'	System	08 Sep 2020 19:04:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:14', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9f854a9f-409f-422a-85e7-9f2ca231e497'	System	08 Sep 2020 19:04:48
User entered 'No (N)'	System	08 Sep 2020 19:04:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:34', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9f854a9f-409f-422a-85e7-9f2ca231e497'	System	08 Sep 2020 19:04:48
User entered 'Yes (Y)'	System	08 Sep 2020 19:04:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:38', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9f854a9f-409f-422a-85e7-9f2ca231e497'	System	08 Sep 2020 19:04:48
User entered '15'	System	08 Sep 2020 19:04:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:41', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9f854a9f-409f-422a-85e7-9f2ca231e497'	System	08 Sep 2020 19:04:48
User entered 'None (1)'	System	08 Sep 2020 19:04:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:44', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9f854a9f-409f-422a-85e7-9f2ca231e497'	System	08 Sep 2020 19:04:48
User entered '08 Sep 2020 12:04'	System	08 Sep 2020 19:04:48

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 5'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:20', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '191d997a-0102-4e7e-b8ef-b664ce407b60'	System	09 Sep 2020 20:01:37
User entered 'None (1)'	System	09 Sep 2020 20:01:37

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:22', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '191d997a-0102-4e7e-b8ef-b664ce407b60'	System	09 Sep 2020 20:01:37
User entered 'No (N)'	System	09 Sep 2020 20:01:37

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:25', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '191d997a-0102-4e7e-b8ef-b664ce407b60'	System	09 Sep 2020 20:01:37
User entered 'No (N)'	System	09 Sep 2020 20:01:37

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:28', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '191d997a-0102-4e7e-b8ef-b664ce407b60'	System	09 Sep 2020 20:01:37
User entered 'None (1)'	System	09 Sep 2020 20:01:37

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:32', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '191d997a-0102-4e7e-b8ef-b664ce407b60'	System	09 Sep 2020 20:01:37
User entered '09 Sep 2020 13:01'	System	09 Sep 2020 20:01:37

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 6'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:48:57', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4d1c5bf6-a1c5-4c1f-8ac3-d017e4af1652'	System	10 Sep 2020 19:49:08
User entered 'None (1)'	System	10 Sep 2020 19:49:08

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:48:59', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4d1c5bf6-a1c5-4c1f-8ac3-d017e4af1652'	System	10 Sep 2020 19:49:08
User entered 'No (N)'	System	10 Sep 2020 19:49:08

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:01', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4d1c5bf6-a1c5-4c1f-8ac3-d017e4af1652'	System	10 Sep 2020 19:49:08
User entered 'No (N)'	System	10 Sep 2020 19:49:08

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:04', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4d1c5bf6-a1c5-4c1f-8ac3-d017e4af1652'	System	10 Sep 2020 19:49:08
User entered 'None (1)'	System	10 Sep 2020 19:49:08

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:06', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4d1c5bf6-a1c5-4c1f-8ac3-d017e4af1652'	System	10 Sep 2020 19:49:08
User entered '10 Sep 2020 12:49'	System	10 Sep 2020 19:49:08

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 7'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:03:43', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4e8156e9-099f-46d5-8e30-0d315343ca55'	System	11 Sep 2020 19:04:12
User entered 'None (1)'	System	11 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:03:45', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4e8156e9-099f-46d5-8e30-0d315343ca55'	System	11 Sep 2020 19:04:12
User entered 'No (N)'	System	11 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:03:47', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4e8156e9-099f-46d5-8e30-0d315343ca55'	System	11 Sep 2020 19:04:12
User entered 'No (N)'	System	11 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:03:49', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4e8156e9-099f-46d5-8e30-0d315343ca55'	System	11 Sep 2020 19:04:12
User entered 'None (1)'	System	11 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:03:53', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4e8156e9-099f-46d5-8e30-0d315343ca55'	System	11 Sep 2020 19:04:12
User entered '11 Sep 2020 12:03'	System	11 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:00:51', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '55c671f0-442a-404e-8f47-f3482780e670'	System	05 Sep 2020 23:01:28
User entered 'None (0)'	System	05 Sep 2020 23:01:28

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:01:02', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '55c671f0-442a-404e-8f47-f3482780e670'	System	05 Sep 2020 23:01:28
User entered 'No interference with activity (1)'	System	05 Sep 2020 23:01:28

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:01:06', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '55c671f0-442a-404e-8f47-f3482780e670'	System	05 Sep 2020 23:01:28
User entered 'None (0)'	System	05 Sep 2020 23:01:28

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:01:08', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '55c671f0-442a-404e-8f47-f3482780e670'	System	05 Sep 2020 23:01:28
User entered 'None (0)'	System	05 Sep 2020 23:01:28

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:01:14', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '55c671f0-442a-404e-8f47-f3482780e670'	System	05 Sep 2020 23:01:28
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Sep 2020 23:01:28

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:01:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '55c671f0-442a-404e-8f47-f3482780e670'	System	05 Sep 2020 23:01:28
User entered 'None (0)'	System	05 Sep 2020 23:01:28

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:01:21', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '55c671f0-442a-404e-8f47-f3482780e670'	System	05 Sep 2020 23:01:28
User entered 'No (N)'	System	05 Sep 2020 23:01:28

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T16:01:23', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '55c671f0-442a-404e-8f47-f3482780e670'	System	05 Sep 2020 23:01:28
User entered '05 Sep 2020 16:01'	System	05 Sep 2020 23:01:28

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '05 Sep 2020 15:43'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 16:13'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '05 Sep 2020 18:13'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 18:43'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:47', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '217f55a1-db32-44e8-b2c5-70db3409f1fc'	System	06 Sep 2020 04:29:05
User entered 'None (0)'	System	06 Sep 2020 04:29:05

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:49', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '217f55a1-db32-44e8-b2c5-70db3409f1fc'	System	06 Sep 2020 04:29:05
User entered 'None (0)'	System	06 Sep 2020 04:29:05

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:51', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '217f55a1-db32-44e8-b2c5-70db3409f1fc'	System	06 Sep 2020 04:29:05
User entered 'None (0)'	System	06 Sep 2020 04:29:05

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:53', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '217f55a1-db32-44e8-b2c5-70db3409f1fc'	System	06 Sep 2020 04:29:05
User entered 'None (0)'	System	06 Sep 2020 04:29:05

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:55', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '217f55a1-db32-44e8-b2c5-70db3409f1fc'	System	06 Sep 2020 04:29:05
User entered 'None (0)'	System	06 Sep 2020 04:29:05

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:57', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '217f55a1-db32-44e8-b2c5-70db3409f1fc'	System	06 Sep 2020 04:29:05
User entered 'None (0)'	System	06 Sep 2020 04:29:05

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:28:59', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '217f55a1-db32-44e8-b2c5-70db3409f1fc'	System	06 Sep 2020 04:29:05
User entered 'No (N)'	System	06 Sep 2020 04:29:05

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-05T21:29:01', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '217f55a1-db32-44e8-b2c5-70db3409f1fc'	System	06 Sep 2020 04:29:05
User entered '05 Sep 2020 21:29'	System	06 Sep 2020 04:29:05

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '05 Sep 2020 19:08'	System	05 Sep 2020 22:59:51
User entered '05 Sep 2020 19:38'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 2'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:21', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3b27c35a-0965-4ea8-8486-94e3e02e388f'	System	06 Sep 2020 19:07:44
User entered 'None (0)'	System	06 Sep 2020 19:07:44

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:23', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3b27c35a-0965-4ea8-8486-94e3e02e388f'	System	06 Sep 2020 19:07:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 19:07:44

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:28', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3b27c35a-0965-4ea8-8486-94e3e02e388f'	System	06 Sep 2020 19:07:44
User entered 'None (0)'	System	06 Sep 2020 19:07:44

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:31', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3b27c35a-0965-4ea8-8486-94e3e02e388f'	System	06 Sep 2020 19:07:44
User entered 'None (0)'	System	06 Sep 2020 19:07:44

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:33', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3b27c35a-0965-4ea8-8486-94e3e02e388f'	System	06 Sep 2020 19:07:44
User entered 'None (0)'	System	06 Sep 2020 19:07:44

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:36', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3b27c35a-0965-4ea8-8486-94e3e02e388f'	System	06 Sep 2020 19:07:44
User entered 'None (0)'	System	06 Sep 2020 19:07:44

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:38', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3b27c35a-0965-4ea8-8486-94e3e02e388f'	System	06 Sep 2020 19:07:44
User entered 'No (N)'	System	06 Sep 2020 19:07:44

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-06T12:07:41', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3b27c35a-0965-4ea8-8486-94e3e02e388f' User entered '06 Sep 2020 12:07'	System	06 Sep 2020 19:07:44
	System	06 Sep 2020 19:07:44

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 3'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:08', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7c4d8dde-7dc6-4d90-9b56-c07a7f20c46d'	System	07 Sep 2020 19:51:38
User entered 'None (0)'	System	07 Sep 2020 19:51:38

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:14', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7c4d8dde-7dc6-4d90-9b56-c07a7f20c46d'	System	07 Sep 2020 19:51:38
User entered 'Some interference with activity (2)'	System	07 Sep 2020 19:51:38

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:18', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7c4d8dde-7dc6-4d90-9b56-c07a7f20c46d'	System	07 Sep 2020 19:51:38
User entered 'No interference with activity (1)'	System	07 Sep 2020 19:51:38

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:23', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7c4d8dde-7dc6-4d90-9b56-c07a7f20c46d'	System	07 Sep 2020 19:51:38
User entered 'None (0)'	System	07 Sep 2020 19:51:38

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:25', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7c4d8dde-7dc6-4d90-9b56-c07a7f20c46d'	System	07 Sep 2020 19:51:38
User entered 'None (0)'	System	07 Sep 2020 19:51:38

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:27', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7c4d8dde-7dc6-4d90-9b56-c07a7f20c46d'	System	07 Sep 2020 19:51:38
User entered 'None (0)'	System	07 Sep 2020 19:51:38

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7c4d8dde-7dc6-4d90-9b56-c07a7f20c46d'	System	07 Sep 2020 19:51:38
User entered 'No (N)'	System	07 Sep 2020 19:51:38

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-07T12:51:32', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7c4d8dde-7dc6-4d90-9b56-c07a7f20c46d'	System	07 Sep 2020 19:51:38
User entered '07 Sep 2020 12:51'	System	07 Sep 2020 19:51:38

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 4'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:03:48', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '21771488-52a6-46de-98de-3bb74790f1e0'	System	08 Sep 2020 19:04:12
User entered 'None (0)'	System	08 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:03:53', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '21771488-52a6-46de-98de-3bb74790f1e0'	System	08 Sep 2020 19:04:12
User entered 'None (0)'	System	08 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:03:56', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '21771488-52a6-46de-98de-3bb74790f1e0'	System	08 Sep 2020 19:04:12
User entered 'None (0)'	System	08 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:03:58', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '21771488-52a6-46de-98de-3bb74790f1e0'	System	08 Sep 2020 19:04:12
User entered 'None (0)'	System	08 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '21771488-52a6-46de-98de-3bb74790f1e0'	System	08 Sep 2020 19:04:12
User entered 'None (0)'	System	08 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:02', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '21771488-52a6-46de-98de-3bb74790f1e0'	System	08 Sep 2020 19:04:12
User entered 'None (0)'	System	08 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:04', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '21771488-52a6-46de-98de-3bb74790f1e0'	System	08 Sep 2020 19:04:12
User entered 'No (N)'	System	08 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-08T12:04:07', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '21771488-52a6-46de-98de-3bb74790f1e0'	System	08 Sep 2020 19:04:12
User entered '08 Sep 2020 12:04'	System	08 Sep 2020 19:04:12

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 5'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:38', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1dda3d41-85d9-4076-aa1e-42fd2ec7787c'	System	09 Sep 2020 20:02:16
User entered 'None (0)'	System	09 Sep 2020 20:02:16

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:42', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1dda3d41-85d9-4076-aa1e-42fd2ec7787c'	System	09 Sep 2020 20:02:16
User entered 'None (0)'	System	09 Sep 2020 20:02:16

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:52', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1dda3d41-85d9-4076-aa1e-42fd2ec7787c'	System	09 Sep 2020 20:02:16
User entered 'No interference with activity (1)'	System	09 Sep 2020 20:02:16

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:01:58', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1dda3d41-85d9-4076-aa1e-42fd2ec7787c'	System	09 Sep 2020 20:02:16
User entered 'None (0)'	System	09 Sep 2020 20:02:16

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:02:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1dda3d41-85d9-4076-aa1e-42fd2ec7787c'	System	09 Sep 2020 20:02:16
User entered 'None (0)'	System	09 Sep 2020 20:02:16

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:02:03', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1dda3d41-85d9-4076-aa1e-42fd2ec7787c'	System	09 Sep 2020 20:02:16
User entered 'None (0)'	System	09 Sep 2020 20:02:16

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:02:05', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1dda3d41-85d9-4076-aa1e-42fd2ec7787c'	System	09 Sep 2020 20:02:16
User entered 'No (N)'	System	09 Sep 2020 20:02:16

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-09T13:02:10', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '1dda3d41-85d9-4076-aa1e-42fd2ec7787c'	System	09 Sep 2020 20:02:16
User entered '09 Sep 2020 13:02'	System	09 Sep 2020 20:02:16

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 6'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:12', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b7dc5e0d-fa74-404f-8db8-3216ed09153c'	System	10 Sep 2020 19:49:41
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b7dc5e0d-fa74-404f-8db8-3216ed09153c'	System	10 Sep 2020 19:49:41
User entered 'Some interference with activity (2)'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:20', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b7dc5e0d-fa74-404f-8db8-3216ed09153c'	System	10 Sep 2020 19:49:41
User entered 'Some interference with activity (2)'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:25', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b7dc5e0d-fa74-404f-8db8-3216ed09153c'	System	10 Sep 2020 19:49:41
User entered 'None (0)'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:27', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b7dc5e0d-fa74-404f-8db8-3216ed09153c'	System	10 Sep 2020 19:49:41
User entered 'None (0)'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b7dc5e0d-fa74-404f-8db8-3216ed09153c'	System	10 Sep 2020 19:49:41
User entered 'None (0)'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:32', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b7dc5e0d-fa74-404f-8db8-3216ed09153c'	System	10 Sep 2020 19:49:41
User entered 'No (N)'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-10T12:49:37', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b7dc5e0d-fa74-404f-8db8-3216ed09153c'	System	10 Sep 2020 19:49:41
User entered '10 Sep 2020 12:49'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	05 Sep 2020 22:53:58
User entered 'Day 7'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:04:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2f147aab-8cac-49d9-b0c4-bb91182200e9'	System	11 Sep 2020 19:04:41
User entered 'No interference with activity (1)'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:04:06', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2f147aab-8cac-49d9-b0c4-bb91182200e9'	System	11 Sep 2020 19:04:41
User entered 'Some interference with activity (2)'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:04:09', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2f147aab-8cac-49d9-b0c4-bb91182200e9'	System	11 Sep 2020 19:04:41
User entered 'Some interference with activity (2)'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:04:13', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2f147aab-8cac-49d9-b0c4-bb91182200e9'	System	11 Sep 2020 19:04:41
User entered 'No interference with activity (1)'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:04:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2f147aab-8cac-49d9-b0c4-bb91182200e9'	System	11 Sep 2020 19:04:41
User entered 'None (0)'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:04:18', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2f147aab-8cac-49d9-b0c4-bb91182200e9'	System	11 Sep 2020 19:04:41
User entered 'None (0)'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:04:26', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2f147aab-8cac-49d9-b0c4-bb91182200e9'	System	11 Sep 2020 19:04:41
User entered 'No (N)'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-11T12:04:33', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2f147aab-8cac-49d9-b0c4-bb91182200e9'	System	11 Sep 2020 19:04:41
User entered '11 Sep 2020 12:04'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 22:53:58

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	10 Sep 2020 19:49:41
User entered 'Day 8'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:02', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3f8bcd8e-a6fa-42ab-9c57-f15195ad960a'	System	12 Sep 2020 22:48:07
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:48:07

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:05', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3f8bcd8e-a6fa-42ab-9c57-f15195ad960a'	System	12 Sep 2020 22:48:07
User entered '12 Sep 2020 15:48'	System	12 Sep 2020 22:48:07

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	11 Sep 2020 19:04:41
User entered 'Day 9'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:21', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '535bf665-c570-46ba-8047-7736e24aa935'	System	13 Sep 2020 20:44:26
User entered 'None (0)'	System	13 Sep 2020 20:44:26

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:23', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '535bf665-c570-46ba-8047-7736e24aa935'	System	13 Sep 2020 20:44:26
User entered '13 Sep 2020 13:44'	System	13 Sep 2020 20:44:26

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	10 Sep 2020 19:49:41
User entered 'Day 8'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:14', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4950befd-bb93-40e3-a559-62ea8fb57c5b'	System	12 Sep 2020 22:48:19
User entered 'Some interference with activity (2)'	System	12 Sep 2020 22:48:19

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:16', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4950befd-bb93-40e3-a559-62ea8fb57c5b'	System	12 Sep 2020 22:48:19
User entered '12 Sep 2020 15:48'	System	12 Sep 2020 22:48:19

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	11 Sep 2020 19:04:41
User entered 'Day 9'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:28', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '56cbfe11-a6e8-4364-ad6d-1bf98986fae4'	System	13 Sep 2020 20:44:34
User entered 'No interference with activity (1)'	System	13 Sep 2020 20:44:34

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:31', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '56cbfe11-a6e8-4364-ad6d-1bf98986fae4'	System	13 Sep 2020 20:44:34
User entered '13 Sep 2020 13:44'	System	13 Sep 2020 20:44:34

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	12 Sep 2020 22:48:19
User entered 'Day 10'	System	12 Sep 2020 22:48:19

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-14T12:01:44', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'dd4ff1d9-d3be-42fa-8009-f0945cd77e4e'	System	14 Sep 2020 19:01:52
User entered 'None (0)'	System	14 Sep 2020 19:01:52

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:18:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-14T12:01:46', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'dd4ff1d9-d3be-42fa-8009-f0945cd77e4e'	System	14 Sep 2020 19:01:52
User entered '14 Sep 2020 12:01'	System	14 Sep 2020 19:01:52

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 22:48:19

US3262145

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 22:48:19

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	10 Sep 2020 19:49:41
User entered 'Day 8'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:24', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5875df55-408a-4d90-a926-ab3f64a88dea'	System	12 Sep 2020 22:48:30
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:48:30

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:26', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5875df55-408a-4d90-a926-ab3f64a88dea'	System	12 Sep 2020 22:48:30
User entered '12 Sep 2020 15:48'	System	12 Sep 2020 22:48:30

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	11 Sep 2020 19:04:41
User entered 'Day 9'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:34', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '88bfe04d-4732-4038-9263-b0b77a538f89'	System	13 Sep 2020 20:44:41
User entered 'None (0)'	System	13 Sep 2020 20:44:41

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:36', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '88bfe04d-4732-4038-9263-b0b77a538f89'	System	13 Sep 2020 20:44:41
User entered '13 Sep 2020 13:44'	System	13 Sep 2020 20:44:41

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	11 Sep 2020 19:04:41
User entered 'Day 8'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:33', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3e88bd5c-d321-4725-a4a1-05b17156f920'	System	12 Sep 2020 22:48:38
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:48:38

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:35', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3e88bd5c-d321-4725-a4a1-05b17156f920'	System	12 Sep 2020 22:48:38
User entered '12 Sep 2020 15:48'	System	12 Sep 2020 22:48:38

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	11 Sep 2020 19:04:41
User entered 'Day 9'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:40', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5c372897-f42d-401f-a50d-64131cfe350c'	System	13 Sep 2020 20:44:44
User entered 'None (0)'	System	13 Sep 2020 20:44:44

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:42', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '5c372897-f42d-401f-a50d-64131cfe350c'	System	13 Sep 2020 20:44:44
User entered '13 Sep 2020 13:44'	System	13 Sep 2020 20:44:44

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	10 Sep 2020 19:49:41
User entered 'Day 8'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:39', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '044912c5-075d-4c9e-ade8-40069e764a33'	System	12 Sep 2020 22:48:44
User entered 'No (N)'	System	12 Sep 2020 22:48:44

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-12T15:48:42', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '044912c5-075d-4c9e-ade8-40069e764a33'	System	12 Sep 2020 22:48:44
User entered '12 Sep 2020 15:48'	System	12 Sep 2020 22:48:44

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:49:41

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
Data entry locked.	System	11 Sep 2020 19:04:41
User entered 'Day 9'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

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)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:45', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'f66ac4e3-744f-4299-93d1-aa20950d81cc'	System	13 Sep 2020 20:44:50
User entered 'No (N)'	System	13 Sep 2020 20:44:50

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-09-13T13:44:47', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'f66ac4e3-744f-4299-93d1-aa20950d81cc'	System	13 Sep 2020 20:44:50
User entered '13 Sep 2020 13:44'	System	13 Sep 2020 20:44:50

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:04:41

US3262145

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:18:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:55
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:04:41

US3262145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:44:01

US3262145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:44:01

US3262145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:44:01

US3262145

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:44:01

US3262145

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 23:44:08

US3262145

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User entered '1'	System	14 Sep 2020 23:44:08

US3262145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:37

US3262145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '21 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:37
	(b) (4)	

US3262145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:37

US3262145

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:37
	(b) (4)	

US3262145

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:27

US3262145

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User entered 'I'	System	06 Oct 2020 23:44:27

US3262145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:48

US3262145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered '28 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:48

US3262145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:48

US3262145

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered empty.	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:48

US3262145

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:07
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:44:52

US3262145

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:34
User entered '1'	System	06 Oct 2020 23:44:52

US3262145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:25

US3262145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '06 Oct 2020'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:25
	(b) (4)	

US3262145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[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 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:25

US3262145

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'VISIT3'	System	06 Oct 2020 23:45:25

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '06 Oct 2020'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49
	(b) (4)	

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '15:25'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '06 Oct 2020 15:25'	System	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '98.6' F	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49
	(b) (4)	

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered empty.	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49
	(b) (4)	

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '76'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'bpm'	System	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '16'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'breaths/min'	System	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '130'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '84'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'mmHg'	System	06 Oct 2020 23:45:49

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55

US3262145

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55

US3262145

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	06 Oct 2020 23:50:35
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	06 Oct 2020 23:50:24
User entered 'No (N)'	Daisy Langarica (b) (4)	06 Oct 2020 23:50:24
	(b) (4)	

US3262145

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered empty; reason for change Data Entry Error	(b) (4)	
	Daisy Langarica (b) (4)	06 Oct 2020 23:50:35
User entered '06 Oct 2020'	(b) (4)	
	Daisy Langarica (b) (4)	06 Oct 2020 23:50:24
	(b) (4)	

US3262145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:50:50

US3262145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '06 Oct 2020'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:50:50
	(b) (4)	

US3262145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered '15:30'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:50:50

US3262145

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '06 Oct 2020 15:30'	System	06 Oct 2020 23:50:50

US3262145

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	12 Feb 2021 22:52:35
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	06 Oct 2020 23:50:53

US3262145

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered '1'	System	06 Oct 2020 23:50:53

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 64'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 71'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 78'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:18:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
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US3262145

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 92'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 99'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3262145

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered 'Day 106'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 22:52:31

US3262145

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:46:27
Data entry locked.	System	08 Aug 2020 22:52:31
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 22:52:31

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2020-12-08T14:53:42', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '32220017-a368-4325-886a-716defac6681'	System	08 Dec 2020 22:53:53
User entered 'No (N)'	System	08 Dec 2020 22:53:53

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2020-12-08T14:53:46', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '32220017-a368-4325-886a-716defac6681'	System	08 Dec 2020 22:53:53
User entered 'No (N)'	System	08 Dec 2020 22:53:53

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-08T14:53:50', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '32220017-a368-4325-886a-716defac6681'	System	08 Dec 2020 22:53:53
User entered '08 Dec 2020 14:53:50'	System	08 Dec 2020 22:53:53

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2020-12-14T09:22:26', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered 'Yes (Y)'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2020-12-14T09:22:34', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered 'Yes (Y)'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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 (105d67672f465197)', Time: '2020-12-14T09:22:41', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 (105d67672f465197)', Time: '2020-12-14T09:22:49', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered 'Yes (Y)'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e' User entered '1'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '1'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e' User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e' User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '1'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '1'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e' User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e' User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e' User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '1'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:29', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered '0'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Please 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 (105d67672f465197)', Time: '2020-12-14T09:23:35', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 (105d67672f465197)', Time: '2020-12-14T09:23:42', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e'	System	14 Dec 2020 17:24:02
User entered 'No (N)'	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-14T09:23:52', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7043412e-9556-4509-9281-097325fb309e' User entered '14 Dec 2020 09:23:52'	System	14 Dec 2020 17:24:02
	System	14 Dec 2020 17:24:02

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2020-12-24T12:44:10', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b365b318-7cb5-4140-a111-6b7489f27fc9'	System	24 Dec 2020 20:44:33
User entered 'No (N)'	System	24 Dec 2020 20:44:33

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2020-12-24T12:44:19', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b365b318-7cb5-4140-a111-6b7489f27fc9'	System	24 Dec 2020 20:44:33
User entered 'No (N)'	System	24 Dec 2020 20:44:33

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-24T12:44:30', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'b365b318-7cb5-4140-a111-6b7489f27fc9' User entered '24 Dec 2020 12:44:30'	System	24 Dec 2020 20:44:33
	System	24 Dec 2020 20:44:33

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 (105d67672f465197)', Time: '2020-12-29T17:48:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3906d76b-5a0f-4fff-b1d1-421e7502ee12'	System	30 Dec 2020 01:48:12
User entered 'No (N)'	System	30 Dec 2020 01:48:12

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2020-12-29T17:48:03', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3906d76b-5a0f-4fff-b1d1-421e7502ee12'	System	30 Dec 2020 01:48:12
User entered 'No (N)'	System	30 Dec 2020 01:48:12

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2020-12-29T17:48:07', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '3906d76b-5a0f-4fff-b1d1-421e7502ee12'	System	30 Dec 2020 01:48:12
User entered '29 Dec 2020 17:48:07'	System	30 Dec 2020 01:48:12

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-01-04T18:52:52', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7443fdb7-8757-45e5-9768-47aa9cdf46a'	System	05 Jan 2021 02:54:38
User entered 'No (N)'	System	05 Jan 2021 02:54:38

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-01-04T18:53:08', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7443fdb7-8757-45e5-9768-47aa9cdf46a'	System	05 Jan 2021 02:54:38
User entered 'No (N)'	System	05 Jan 2021 02:54:38

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-01-04T18:54:37', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '7443fdb7-8757-45e5-9768-47aa9cdf46a'	System	05 Jan 2021 02:54:38
User entered '04 Jan 2021 18:54:37'	System	05 Jan 2021 02:54:38

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-01-11T07:16:54', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '17594739-62a6-4198-9b3b-70219b187dfd'	System	11 Jan 2021 15:17:01
User entered 'No (N)'	System	11 Jan 2021 15:17:01

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-01-11T07:16:56', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '17594739-62a6-4198-9b3b-70219b187dfd'	System	11 Jan 2021 15:17:01
User entered 'No (N)'	System	11 Jan 2021 15:17:01

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-01-11T07:16:59', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '17594739-62a6-4198-9b3b-70219b187dfd'	System	11 Jan 2021 15:17:01
User entered '11 Jan 2021 07:16:59'	System	11 Jan 2021 15:17:01

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-01-18T07:39:41', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'eccbf6b7-d0b0-4058-a0a8-638cdbbc6d05'	System	18 Jan 2021 15:39:52
User entered 'No (N)'	System	18 Jan 2021 15:39:52

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-01-18T07:39:44', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'eccbf6b7-d0b0-4058-a0a8-638cdbbc6d05'	System	18 Jan 2021 15:39:52
User entered 'No (N)'	System	18 Jan 2021 15:39:52

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-01-18T07:39:48', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'eccbf6b7-d0b0-4058-a0a8-638cdbbc6d05'	System	18 Jan 2021 15:39:52
User entered '18 Jan 2021 07:39:48'	System	18 Jan 2021 15:39:52

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-01-25T12:08:47', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ce36ca0b-76bc-4182-9223-b5b2681d46bd'	System	25 Jan 2021 20:12:28
User entered 'No (N)'	System	25 Jan 2021 20:12:28

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-01-25T12:08:50', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ce36ca0b-76bc-4182-9223-b5b2681d46bd'	System	25 Jan 2021 20:12:28
User entered 'No (N)'	System	25 Jan 2021 20:12:28

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-01-25T12:08:52', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ce36ca0b-76bc-4182-9223-b5b2681d46bd' User entered '25 Jan 2021 12:08:52'	System	25 Jan 2021 20:12:28
	System	25 Jan 2021 20:12:28

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

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 (105d67672f465197)', Time: '2021-02-01T07:07:33', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9f6c763b-353d-43ff-bb6d-826394060280'	System	01 Feb 2021 14:07:43
User entered 'No (N)'	System	01 Feb 2021 14:07:43

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-02-01T07:07:36', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9f6c763b-353d-43ff-bb6d-826394060280'	System	01 Feb 2021 14:07:43
User entered 'No (N)'	System	01 Feb 2021 14:07:43

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-02-01T07:07:39', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '9f6c763b-353d-43ff-bb6d-826394060280'	System	01 Feb 2021 14:07:43
User entered '01 Feb 2021 07:07:39'	System	01 Feb 2021 14:07:43

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-02-09T13:49:36', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '0c30279e-463c-4103-97be-2fd7d8445be2'	System	09 Feb 2021 21:49:47
User entered 'No (N)'	System	09 Feb 2021 21:49:47

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-02-09T13:49:39', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '0c30279e-463c-4103-97be-2fd7d8445be2'	System	09 Feb 2021 21:49:47
User entered 'No (N)'	System	09 Feb 2021 21:49:47

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-02-09T13:49:44', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '0c30279e-463c-4103-97be-2fd7d8445be2'	System	09 Feb 2021 21:49:47
User entered '09 Feb 2021 13:49:44'	System	09 Feb 2021 21:49:47

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-02-15T09:44:38', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '39c0ade9-6566-4c88-8b18-ffc01dc99022'	System	15 Feb 2021 17:44:48
User entered 'No (N)'	System	15 Feb 2021 17:44:48

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-02-15T09:44:40', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '39c0ade9-6566-4c88-8b18-ffc01dc99022'	System	15 Feb 2021 17:44:48
User entered 'No (N)'	System	15 Feb 2021 17:44:48

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-02-15T09:44:45', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '39c0ade9-6566-4c88-8b18-ffc01dc99022'	System	15 Feb 2021 17:44:48
User entered '15 Feb 2021 09:44:45'	System	15 Feb 2021 17:44:48

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-02-22T13:09:05', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '25a01a4c-f168-4f7a-b6e1-97d700ef2b82'	System	22 Feb 2021 21:09:14
User entered 'No (N)'	System	22 Feb 2021 21:09:14

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-02-22T13:09:07', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '25a01a4c-f168-4f7a-b6e1-97d700ef2b82'	System	22 Feb 2021 21:09:14
User entered 'No (N)'	System	22 Feb 2021 21:09:14

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-02-22T13:09:10', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '25a01a4c-f168-4f7a-b6e1-97d700ef2b82'	System	22 Feb 2021 21:09:14
User entered '22 Feb 2021 13:09:10'	System	22 Feb 2021 21:09:14

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-03-02T13:37:26-08:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2e2414c2-b92d-4c42-bc9c-622d3b7b76a1'	System	02 Mar 2021 21:37:38
User entered 'No (N)'	System	02 Mar 2021 21:37:38

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-03-02T13:37:31-08:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2e2414c2-b92d-4c42-bc9c-622d3b7b76a1'	System	02 Mar 2021 21:37:38
User entered 'No (N)'	System	02 Mar 2021 21:37:38

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-03-02T13:37:34-08:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '2e2414c2-b92d-4c42-bc9c-622d3b7b76a1'	System	02 Mar 2021 21:37:38
User entered '02 Mar 2021 13:37:34'	System	02 Mar 2021 21:37:38

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-03-08T09:58:22-08:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'c63ed043-902c-4779-9dda-7785d5997b26'	System	08 Mar 2021 17:58:31
User entered 'No (N)'	System	08 Mar 2021 17:58:31

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-03-08T09:58:24-08:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'c63ed043-902c-4779-9dda-7785d5997b26'	System	08 Mar 2021 17:58:31
User entered 'No (N)'	System	08 Mar 2021 17:58:31

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-03-08T09:58:27-08:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'c63ed043-902c-4779-9dda-7785d5997b26'	System	08 Mar 2021 17:58:31
User entered '08 Mar 2021 09:58:27'	System	08 Mar 2021 17:58:31

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-03-22T08:25:40-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '8d462fa2-a95e-423f-9c56-8b28536eb291'	System	22 Mar 2021 15:25:48
User entered 'No (N)'	System	22 Mar 2021 15:25:48

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-03-22T08:25:42-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '8d462fa2-a95e-423f-9c56-8b28536eb291'	System	22 Mar 2021 15:25:48
User entered 'No (N)'	System	22 Mar 2021 15:25:48

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-03-22T08:25:45-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '8d462fa2-a95e-423f-9c56-8b28536eb291'	System	22 Mar 2021 15:25:48
User entered '22 Mar 2021 08:25:45'	System	22 Mar 2021 15:25:48

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-03-29T08:35:29-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '107b4d03-5e56-475f-8806-18db0809f51b'	System	29 Mar 2021 15:35:37
User entered 'No (N)'	System	29 Mar 2021 15:35:37

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-03-29T08:35:30-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '107b4d03-5e56-475f-8806-18db0809f51b'	System	29 Mar 2021 15:35:37
User entered 'No (N)'	System	29 Mar 2021 15:35:37

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-03-29T08:35:32-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '107b4d03-5e56-475f-8806-18db0809f51b'	System	29 Mar 2021 15:35:37
User entered '29 Mar 2021 08:35:32'	System	29 Mar 2021 15:35:37

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-04-05T09:28:26-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '95e74288-20a5-49ce-b24c-bd99dcf52cb7'	System	05 Apr 2021 16:29:10
User entered 'No (N)'	System	05 Apr 2021 16:29:10

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-04-05T09:28:28-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '95e74288-20a5-49ce-b24c-bd99dcf52cb7'	System	05 Apr 2021 16:29:10
User entered 'No (N)'	System	05 Apr 2021 16:29:10

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-04-05T09:28:31-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '95e74288-20a5-49ce-b24c-bd99dcf52cb7'	System	05 Apr 2021 16:29:10
User entered '05 Apr 2021 09:28:31'	System	05 Apr 2021 16:29:10

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-04-12T09:21:44-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4fc2261f-6a3a-4d89-ab9d-22775780edf5'	System	12 Apr 2021 16:22:04
User entered 'No (N)'	System	12 Apr 2021 16:22:04

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-04-12T09:21:45-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4fc2261f-6a3a-4d89-ab9d-22775780edf5'	System	12 Apr 2021 16:22:04
User entered 'No (N)'	System	12 Apr 2021 16:22:04

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-04-12T09:21:48-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: '4fc2261f-6a3a-4d89-ab9d-22775780edf5'	System	12 Apr 2021 16:22:04
User entered '12 Apr 2021 09:21:48'	System	12 Apr 2021 16:22:04

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-04-19T07:25:48-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'efeeeb0a-f881-4ce0-bc0c-70b775d3b74a'	System	19 Apr 2021 14:25:57
User entered 'No (N)'	System	19 Apr 2021 14:25:57

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-04-19T07:25:50-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'efeeeb0a-f881-4ce0-bc0c-70b775d3b74a'	System	19 Apr 2021 14:25:57
User entered 'No (N)'	System	19 Apr 2021 14:25:57

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-04-19T07:25:55-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'efeeeb0a-f881-4ce0-bc0c-70b775d3b74a'	System	19 Apr 2021 14:25:57
User entered '19 Apr 2021 07:25:55'	System	19 Apr 2021 14:25:57

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[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 (105d67672f465197)', Time: '2021-04-26T10:50:03-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'd4161e48-1404-46c6-ac58-e6f42900cede' User entered 'No (N)'	System	26 Apr 2021 17:50:15
	System	26 Apr 2021 17:50:15

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

Have you been exposed to someone with 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 (105d67672f465197)', Time: '2021-04-26T10:50:06-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'd4161e48-1404-46c6-ac58-e6f42900cede' User entered 'No (N)'	System	26 Apr 2021 17:50:15
	System	26 Apr 2021 17:50:15

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-04-26T10:50:09-07:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'd4161e48-1404-46c6-ac58-e6f42900cede' User entered '26 Apr 2021 10:50:09'	System	26 Apr 2021 17:50:15
	System	26 Apr 2021 17:50:15

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:46:27

US3262145

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:46:27
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:46:27

US3262145

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:18:25

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:12:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-03-02T13:37:13-08:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ce418916-eeb6-48dd-9520-79d556bbcb0c'	System	02 Mar 2021 21:37:24
User entered 'No (N)'	System	02 Mar 2021 21:37:24

US3262145

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:18:25

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:12:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (105d67672f465197)', Time: '2021-03-02T13:37:20-08:00', User OID: 'PatientReportedOutcome (US3262145)', ODM File OID: 'ce418916-eeb6-48dd-9520-79d556bbcb0c' User entered '02 Mar 2021 13:37:20'	System	02 Mar 2021 21:37:24
	System	02 Mar 2021 21:37:24

US3262145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 23:55:30

US3262145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:53
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 23:55:30

US3262145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 23:55:30

US3262145

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 23:55:30

US3262145

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User signature succeeded.	Atoya Adams (b) (4)	05 Mar 2021 18:40:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 23:55:40

US3262145

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 15:19:55
User entered 'I'	System	02 Nov 2020 23:55:40

US3262145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	15 Dec 2020 17:35:17

US3262145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered '08 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	15 Dec 2020 17:35:17

US3262145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4) (b) (4)	15 Dec 2020 17:35:17

US3262145

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered empty.	Daisy Langarica (b) (4) (b) (4)	15 Dec 2020 17:35:17

US3262145

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	15 Dec 2020 17:35:06

US3262145

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:18
User entered 'I'	System	15 Dec 2020 17:35:06

US3262145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	04 Jan 2021 18:05:00

US3262145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	04 Jan 2021 18:05:48
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	04 Jan 2021 18:05:48
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	04 Jan 2021 18:05:48
User entered '04 Jan 2021' reason for change: Data Entry Error	Daisy Langarica (b) (4)	04 Jan 2021 18:05:48
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	04 Jan 2021 18:05:00
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of Informed Consent'. Please review and reconcile.' (Site from System).	System	04 Jan 2021 18:05:00
User entered '04 Jan 2020'	Daisy Langarica (b) (4)	04 Jan 2021 18:05:00

US3262145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4) (b) (4)	04 Jan 2021 18:05:00

US3262145

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered empty.	Daisy Langarica (b) (4) (b) (4)	04 Jan 2021 18:05:00

US3262145

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	04 Jan 2021 18:05:53

US3262145

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:18
User entered '1'	System	04 Jan 2021 18:05:53

US3262145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	23 Feb 2021 17:33:17
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	23 Feb 2021 17:33:12
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	23 Feb 2021 17:33:12

US3262145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered '04 Feb 2021'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:33:12

US3262145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:33:17
User entered empty.	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:33:12

US3262145

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered empty.	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:33:12

US3262145

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 17:59:18
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:33:21

US3262145

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:18
User entered 'I'	System	23 Feb 2021 17:33:21

US3262145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:48:12

US3262145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '02 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:48:12

US3262145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[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 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:48:12

US3262145

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User entered 'VISIT4'	System	05 Mar 2021 15:48:12

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '02 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '10:35'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User entered '02 Mar 2021 10:35'	System	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '99.0' F	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '76'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User entered 'bpm'	System	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '14'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User entered 'breaths/min'	System	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '133'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User entered 'mmHg'	System	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '84'	(b) (4) Daisy Langarica (b) (4)	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User entered 'mmHg'	System	31 Mar 2021 21:06:31

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44

US3262145

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44

US3262145

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:48:18

US3262145

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:48:18

US3262145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:48:37

US3262145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '02 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:48:37

US3262145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '10:40'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:48:37

US3262145

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User entered '02 Mar 2021 10:40'	System	05 Mar 2021 15:48:37

US3262145

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:48:43

US3262145

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:37:44
User entered '1'	System	05 Mar 2021 15:48:43

US3262145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	05 Apr 2021 17:03:20
	(b) (4)	

US3262145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
	(b) (4)	
User entered '05 Apr 2021'	Daisy Langarica (b) (4)	05 Apr 2021 17:03:20
	(b) (4)	

US3262145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Daisy Langarica (b) (4)	05 Apr 2021 17:03:20
	(b) (4)	

US3262145

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	05 Apr 2021 17:03:20
	(b) (4)	

US3262145

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
	(b) (4)	
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	05 Apr 2021 17:03:24
	(b) (4)	

US3262145

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 17:03:24

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:25

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:43
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:20:42
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per response " Yes, the sample was collected for the illness visit day 1" , however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 14 DEC 2020 in EDC, please verify and update the data as needed, else clarify. Thank you.' (Site from DM).		15 Jan 2021 14:40:54
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per response " Yes, the sample was collected for the illness visit day 1" , however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 14 DEC 2020 in EDC, please verify and update the data as needed, else clarify. Thank you.' answered with 'THIS HAS ALREADY BEEN ENTERED ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 15:42:25
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per response " Yes, the sample was collected for the illness visit day 1" , however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 14 DEC 2020 in EDC, please verify and update the data as needed, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 11:02:36
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 14 DEC 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		24 Dec 2020 11:02:36

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:25

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 14 DEC 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Yes, the sample was collected for the illness visit day 1' (Site from DM). User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 14 DEC 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). User entered '14 Dec 2020'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:15:33
	(b) (4), (b) (6)	22 Dec 2020 12:05:32
	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 16:59:57

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:25

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:43
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:20:42
User entered '12:00'	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 16:59:57

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:25

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:43
User entered '14 Dec 2020 12:00'	System	18 Dec 2020 16:59:57

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:25

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:43
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User closed query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:26:02
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:20:42
Query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' answered with 'CORRECT AS IS ' (Site from CRA).	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 15:42:42
User opened query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 19:00:42
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	-Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 16:59:57

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:25

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:43
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:20:42
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 16:59:57

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 1 (Day 1)'	(b) (4) Daisy Langarica (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '14 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '94'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '38.9' C	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Daisy Langarica (b) (4) (b) (4)	21 Dec 2020 15:36:21

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 2 (Day 2)'	(b) (4) Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '15 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '93'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '102.2' F	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:36:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 3 (Day 3)'	(b) (4) Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '16 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '93'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '100.2' F	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:37:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 4 (Day 4)'	(b) (4) Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '17 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '93'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '100.6' F	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:39:06

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 5 (Day 5)'	(b) (4) Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '18 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '93'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '100.1' F	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:40:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 6 (Day 6)'	(b) (4) Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '19 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '91'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '101' F	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Severe (Severe)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Severe (Severe)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:42:12

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 7 (Day 7)'	(b) (4) Atoya Adams (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '20 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '93'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	21 Dec 2020 21:43:50

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '98.6' F	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:43:50

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 8 (Day 8)'	(b) (4) Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '21 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '93'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '98.3' F	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:57:55

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 9 (Day 9)'	(b) (4) Atoya Adams (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '22 Dec 2020'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '92'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	22 Dec 2020 23:14:39

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '98.7' F	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	22 Dec 2020 23:14:39

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 10 (Day 10)'	(b) (4) Atoya Adams (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '23 Dec 2020'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '93'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '98.4' F	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 03:19:40

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 11 (Day 11)'	(b) (4) Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '24 Dec 2020'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '92'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	24 Dec 2020 22:15:30

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '98.6' F	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:15:30

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 12 (Day 12)'	(b) (4) Atoya Adams (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '25 Dec 2020'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '93'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '98.4' F	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	25 Dec 2020 19:37:59

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 13 (Day 13)'	(b) (4) Atoya Adams (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '26 Dec 2020'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '93'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '98.1' F	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Moderate (Moderate)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:45:26

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 14 (Day 14)'	(b) (4) Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '27 Dec 2020'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '98'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '97.1' F	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:14:46

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 15 (Day 15)'	(b) (4) Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '28 Dec 2020'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '97'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '97.8' F	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'Mild (Mild)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 01:56:14

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Day 16 (Day 16)'	(b) (4) Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '29 Dec 2020'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '0'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '96'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User entered '%'	System	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered '98.2' F	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:49
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:32:52
User entered 'None (None)'	Atoya Adams (b) (4) (b) (4)	30 Dec 2020 00:53:28

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:34:55
User entered '14 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:01:43

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Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:34:55
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:01:43

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:34:55
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	24 Dec 2020 08:57:32
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 'noted' (Site from System).	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:02:07
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	18 Dec 2020 17:01:43
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:01:43

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:34:55
User entered '14 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:01:43

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:34:55
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:01:43

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:34:55
User entered empty.	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:01:43

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:34:55
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:01:43

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Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:34:55
User entered empty.	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:01:43

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:34:55
User entered empty.	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:01:43

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Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:25

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:54
User entered '1'	System	18 Dec 2020 17:01:43

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered '15 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered '26 Dec 2020' reason for change: New Information	Atoya Adams (b) (4) (b) (4)	28 Dec 2020 00:15:59
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User closed query 'Per CDM: Please note that lowest O2 saturation between 19-Dec-20 and 26-Dec-20 is 91%, Kindly check and correct the Oxygen saturation or else clarify. thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 11:27:02
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:24:12
Query 'Per CDM: Please note that lowest O2 saturation between 19-Dec-20 and 26-Dec-20 is 91%, Kindly check and correct the Oxygen saturation or else clarify. thanks ' answered with 'updated ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	21 Apr 2021 16:51:54
DataPoint Un-verified.	Daisy Langarica (b) (4) (b) (4)	21 Apr 2021 16:51:32
User entered '91' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	21 Apr 2021 16:51:32
User opened query 'Per CDM: Please note that lowest O2 saturation between 19-Dec-20 and 26-Dec-20 is 91%, Kindly check and correct the Oxygen saturation or else clarify. thanks ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:34:11
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered '93'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered '19 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered '25 Dec 2020' reason for change: New Information	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:39:47
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

Folder: Covid-19 Assessment 14 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:25

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

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[Start Date](#)

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User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

US3262145

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User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Generated On: 09 Jun 2021 16:18:25

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Generated On: 09 Jun 2021 16:18:25

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
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[Evidence of Shock Requires Vasopressors](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
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User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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[Neurologic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:08:59
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:36:45
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:45:27

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:18:25

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:04
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:02
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	18 Dec 2020 17:02:26

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:18:25

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F619060834 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:05:51
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F619060834 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you. ' answered with 'CORRECT AS IS COLLECTED 16 DEC 2020 FOR D3 ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:38:38
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession # 1F619060834 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:01:16
User accepted default value 'Day 3 (Day 3)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:18:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:18:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered '16 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:18:25

[Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F621594284 is reported with 18DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:03:02
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F621594284 is reported with 18DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:01:40
User accepted default value 'Day 5 (Day 5)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:18:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:18:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F621594284 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you.' (Site from DM). Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F621594284 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you.' answered with 'CORRECT AS IS NO QUERIES IN PRECLARUS ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Daisy Langarica (b) (4) (b) (4)	01 Mar 2021 10:05:55 23 Feb 2021 17:39:28
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession # 1F621594284 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you.' (Site from DM). User entered '18 Dec 2020'	(b) (4), (b) (6) Daisy Langarica (b) (4) (b) (4)	16 Feb 2021 18:26:20 10 Feb 2021 06:02:58 01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:18:25

[Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F604315748 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank yo' canceled (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:03:29
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F604315748 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank yo' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:02:33
User accepted default value 'Day 7 (Day 7)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:18:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:18:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User closed query ' Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F604315748 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you. ' (Site from DM). Query ' Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F604315748 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you. ' answered with 'CORRECT AS IS COLLECTED 20 DE 2020 NO AVAILABLE QUERIES ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Daisy Langarica (b) (4) (b) (4) (b) (4), (b) (6)	01 Mar 2021 10:06:06 23 Feb 2021 17:40:07 16 Feb 2021 18:26:20
User opened query ' Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession # 1F604315748 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you. ' (Site from DM). User entered '20 Dec 2020'	(b) (4) Daisy Langarica (b) (4) (b) (4)	10 Feb 2021 06:03:26 01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:18:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:18:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:18:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F602670758 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you ' (Site from DM). Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F602670758 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 10:06:10
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F602670758 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you ' answered with 'CORRECT AS IS NO QUERIES IN PRECLARUS ' (Site from DM). DataPoint Verified.	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:40:32
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F602670758 is reported with 16DEC2020 date of Collection and which is missing in EDC. Please review the Accession # in Preclarus and confirm the correct date and sample label then record on the Saliva collection form. Thank you ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered '22 Dec 2020'	(b) (4), (b) (6)	10 Feb 2021 06:04:17
	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:18:25

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621026476 is reported with 16DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you. (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:06:14
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621026476 is reported with 16DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you. answered with 'CORRECT AS IS ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:40:43
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621026476 is reported with 16DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you. (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:22:10
User accepted default value 'Day 14 (Day 14)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:18:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:18:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered '27 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:18:25

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F600646756 is reported with 16DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you. (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:06:18
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F600646756 is reported with 16DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you. answered with 'CORRECT AS IS ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:40:57
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F600646756 is reported with 16DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you. (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:23:35
User accepted default value 'Day 21 (Day 21)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:18:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:18:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered '03 Jan 2021'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:18:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:18:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:18:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:26:20
User entered '13 Jan 2021'	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:20:01

US3262145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User closed query 'Per ETRTR: According to AE narrative, saliva has been collected. Please complete data entry within Saliva Collection page, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:24:26
Query 'Per ETRTR: According to AE narrative, saliva has been collected. Please complete data entry within Saliva Collection page, thanks.' answered with 'ENTERED THANK YOU ' (Site from CRA).	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:21:11
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:37:31
User opened query 'Per ETRTR: According to AE narrative, saliva has been collected. Please complete data entry within Saliva Collection page, thanks.' (Site from CRA).		04 Jan 2021 19:00:15
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 16:59:55

US3262145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:31
User entered '14 Dec 2020'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 16:59:55

US3262145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[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 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:31
User entered 'Clinic (Clinic)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 16:59:55

US3262145

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User entered 'SICKD1'	System	29 Dec 2020 16:59:55

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered '14 Dec 2020'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered '12:25'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User entered '14 Dec 2020 12:25'	System	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered '60' in	Atoya Adams (b) (4)	29 Dec 2020 17:02:11
DataPoint set to visible.	(b) (4) System	29 Dec 2020 16:59:55

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 22:55:04
Query 'Data is required. Please provide.' answered with 'This was not allowed to be collected by the patient' (Site from System).	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:34
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Dec 2020 17:02:11
User entered empty.	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11
DataPoint set to visible.	System	29 Dec 2020 16:59:55

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered '38.9' C	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered 'Oral (Oral)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered empty.	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User closed query 'Per ETRTR: Please consider AE reporting if required according to clinical significance, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:24:47
Query 'Per ETRTR: Please consider AE reporting if required according to clinical significance, thanks.' answered with 'NCS PER PI ' (Site from CRA).	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:16:21
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:37:41
User opened query 'Per ETRTR: Please consider AE reporting if required according to clinical significance, thanks.' (Site from CRA).		04 Jan 2021 18:59:06
User entered '111'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User entered 'bpm'	System	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered '18'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User entered 'breaths/min'	System	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered '124'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User entered 'mmHg'	System	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:41
User entered '83'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User entered 'mmHg'	System	29 Dec 2020 17:02:11

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58

US3262145

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58

US3262145

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:58
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:46

US3262145

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:37:58
User entered '14 Dec 2020'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:46

US3262145

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:18:25

[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 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:38:13
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:55

US3262145

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:18:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:56:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:38:13
User entered '14 Dec 2020'	Atoya Adams (b) (4) (b) (4)	29 Dec 2020 17:02:55

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:38:45
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:54:00

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:38:45
User entered '13 Jan 2021'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:54:00

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[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 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:38:45
User entered 'Clinic (Clinic)'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:54:00

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User entered 'SICKD28'	System	14 Jan 2021 00:54:00

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered '13 Jan 2021'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered '11:25'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User entered '13 Jan 2021 11:25'	System	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered '60' in	Daisy Langarica (b) (4)	14 Jan 2021 00:55:36
DataPoint set to visible.	(b) (4) System	14 Jan 2021 00:54:00

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered '229.8' lb	Daisy Langarica (b) (4)	14 Jan 2021 00:55:36
DataPoint set to visible.	(b) (4) System	14 Jan 2021 00:54:00

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered '99.2' F	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered 'Oral (Oral)'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered empty.	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered '80'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User entered 'bpm'	System	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered '16'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User entered 'breaths/min'	System	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered '146'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User entered 'mmHg'	System	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:39:53
User entered '88'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User entered 'mmHg'	System	14 Jan 2021 00:55:36

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:40:08
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:45

US3262145

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:40:08
User entered '13 Jan 2021'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:45

US3262145

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 16:18:25

[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 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:40:24
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:54

US3262145

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 16:18:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:33
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 07:24:21
Query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'THIS HAS BEEN SENT PLEASE SEE TRACKING NUMBER: 945470590683' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	01 Feb 2021 20:23:16
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had 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 10:14:33
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:40:24
User entered '13 Jan 2021'	Daisy Langarica (b) (4) (b) (4)	14 Jan 2021 00:55:54

US3262145

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

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:41:29
	(b) (4)	

US3262145

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

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '28 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:41:29
	(b) (4)	

US3262145

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

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:41:29
	(b) (4)	

US3262145

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

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 17:41:29

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '28 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:57:17
	(b) (4)	

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:32:08

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:57:17

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
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 03:32:08

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '28 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:57:17
	(b) (4)	

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Placebo (Placebo)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:57:17

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Placebo (Placebo)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:57:17

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Placebo (Placebo)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:57:17

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:57:17

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered '1'	System	28 Jan 2021 17:57:17

US3262145

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:25

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered '1'	System	28 Jan 2021 17:57:17

US3262145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered empty.	System	28 Jan 2021 17:58:45
DataPoint set to visible.	System	28 Jan 2021 17:57:17

US3262145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered empty.	System	28 Jan 2021 17:58:45
DataPoint set to visible.	System	28 Jan 2021 17:57:17

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4) (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '28 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '08:39'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered '28 Jan 2021 08:39'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered '98.8' F	Daisy Langarica (b) (4) (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '91'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'bpm'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '18'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'breaths/min'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '140'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'mmHg'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '89'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'mmHg'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered missing code ND - Not Done.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered empty.	System	28 Jan 2021 17:58:45
DataPoint set to visible.	System	28 Jan 2021 17:57:17

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4) (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '28 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '09:21'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered '28 Jan 2021 09:21'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	28 Apr 2021 16:42:37
User entered '98.8' F	Daisy Langarica (b) (4) (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45
	(b) (4)	

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '87'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'bpm'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '16'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'breaths/min'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '122'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'mmHg'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '87'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:45

US3262145

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'mmHg'	System	28 Jan 2021 17:58:45

US3262145

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:54

US3262145

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '28 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:58:54
	(b) (4)	

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:59:35

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:59:35
	(b) (4)	

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:59:35
	(b) (4)	

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'mRNA-1273'	System	28 Jan 2021 17:59:35
DataPoint set to visible.	System	28 Jan 2021 17:57:17

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '28 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:59:35
	(b) (4)	

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '08:51'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:59:35

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered '28 Jan 2021 08:51'	System	28 Jan 2021 17:59:35

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:59:35

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'ONCE'	System	28 Jan 2021 17:59:35

US3262145

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

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 17:59:35

US3262145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:41:45

US3262145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '28 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:41:45
	(b) (4)	

US3262145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '08:44'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:41:45

US3262145

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered '28 Jan 2021 08:44'	System	28 Jan 2021 17:41:45

US3262145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:41:59

US3262145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:18:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '28 Jan 2021'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:41:59
	(b) (4)	

US3262145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '08:42'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:41:59
	(b) (4)	

US3262145

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered '28 Jan 2021 08:42'	System	28 Jan 2021 17:41:59

US3262145

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

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	28 Jan 2021 17:59:39

US3262145

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

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:28:01
User entered '1'	System	28 Jan 2021 17:59:39

US3262145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:28:37
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	06 Feb 2021 00:51:01

US3262145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:28:37
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '05 Feb 2021'	Daisy Langarica (b) (4)	06 Feb 2021 00:51:01

US3262145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:28:37
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Contact Made (CONTACT MADE)'	Daisy Langarica (b) (4)	06 Feb 2021 00:51:01

US3262145

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:28:37
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	Daisy Langarica (b) (4)	06 Feb 2021 00:51:01

US3262145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:28:37
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	06 Feb 2021 00:50:44

US3262145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:28:37
User entered '1'	System	06 Feb 2021 00:50:44

US3262145

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:28:37
User entered '1'	System	06 Feb 2021 00:50:44
DataPoint set to visible.	System	06 Feb 2021 00:50:44

US3262145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User closed query 'Per GCL Lab recon: Immunogenicity: PPD has Immuno sample dated 2MAR2021 Barcode: 1F600227381 labelled as OL-D29 , however subject has two dose in OL-phase and will not have Immuno sample collected at this Visit. Please review the Preclarus and if the sample was collected in error at OL-D29 visit then consider the sample as additional sample and record OL-Immuno under UNSCH visit and also update the Preclarus. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:16:40
Query 'Per GCL Lab recon: Immunogenicity: PPD has Immuno sample dated 2MAR2021 Barcode: 1F600227381 labelled as OL-D29 , however subject has two dose in OL-phase and will not have Immuno sample collected at this Visit. Please review the Preclarus and if the sample was collected in error at OL-D29 visit then consider the sample as additional sample and record OL-Immuno under UNSCH visit and also update the Preclarus. Thank you' answered with 'open label day 29 drawn 02 mar 2021' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:12:49
User opened query 'Per GCL Lab recon: Immunogenicity: PPD has Immuno sample dated 2MAR2021 Barcode: 1F600227381 labelled as OL-D29 , however subject has two dose in OL-phase and will not have Immuno sample collected at this Visit. Please review the Preclarus and if the sample was collected in error at OL-D29 visit then consider the sample as additional sample and record OL-Immuno under UNSCH visit and also update the Preclarus. Thank you' (Site from DM).		23 Mar 2021 07:16:20
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	05 Mar 2021 15:42:59

US3262145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '02 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:42:59

US3262145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Clinic (Clinic)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:42:59

US3262145

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'OLD29'	System	05 Mar 2021 15:42:59

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User accepted default value 'Pre-Dose (PREDOSE)'	Daisy Langarica (b) (4) (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '02 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '10:35'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered '02 Mar 2021 10:35'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '99.0' F	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '76'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'bpm'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '14'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'breaths/min'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '133'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'mmHg'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '84'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'mmHg'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User accepted default value 'Post-Dose (POSTDOSE)'	Daisy Langarica (b) (4) (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '02 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '11:14'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered '02 Mar 2021 11:14'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '98.0' F	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Oral (Oral)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '74'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'bpm'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '16'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'breaths/min'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '132'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'mmHg'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '81'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'mmHg'	System	05 Mar 2021 15:47:56

US3262145

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:43:09

US3262145

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '02 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:43:09

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:43:42

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:43:42

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:43:42
	(b) (4)	

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'mRNA-1273'	System	05 Mar 2021 15:43:42
DataPoint set to visible.	System	06 Feb 2021 00:50:44

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '02 Mar 2021'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:43:42

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '10:44'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:43:42

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered '02 Mar 2021 10:44'	System	05 Mar 2021 15:43:42

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:43:42

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'ONCE'	System	05 Mar 2021 15:43:42

US3262145

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 15:43:42

US3262145

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) Daisy Langarica (b) (4)	05 Mar 2021 15:43:46

US3262145

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:38
User entered '1'	System	05 Mar 2021 15:43:46

US3262145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:24:43
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:22:41

US3262145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:24:43
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:22:41

US3262145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:24:43
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:22:41

US3262145

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:24:43
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:22:41

US3262145

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:24:43
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:23:02

US3262145

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:24:43
User entered 'I'	System	10 Mar 2021 23:23:02

US3262145

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:06:35

US3262145

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:06:35

US3262145

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:06:35

US3262145

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User entered 'OLD57'	System	30 Mar 2021 19:06:35

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '10:16'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User entered '30 Mar 2021 10:16'	System	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '99.3' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '73'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User entered 'bpm'	System	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '14'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User entered 'breaths/min'	System	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '134'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User entered 'mmHg'	System	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '82'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User entered 'mmHg'	System	30 Mar 2021 19:07:03

US3262145

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:25

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22

US3262145

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:20

US3262145

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:20

US3262145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:37

US3262145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:37

US3262145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
User entered '10:19'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:37

US3262145

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:47:22
User entered '30 Mar 2021 10:19'	System	30 Mar 2021 19:07:37

US3262145

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:18:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:33:19
User signature succeeded.	Atoya Adams (b) (4)	03 May 2021 19:55:00
User closed query 'Per CDM: Per previous query response "UPDATED"; however, the update for subject's Diary Dose 2 'Joints Aches' Symptom lasted beyond day 7 post injection is not obvious? Please provide location of update such as the log line number updated. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 07:42:39
Query 'Per CDM: Per previous query response "UPDATED"; however, the update for subject's Diary Dose 2 'Joints Aches' Symptom lasted beyond day 7 post injection is not obvious? Please provide location of update such as the log line number updated. Thank you. ' answered with 'subject reported whole body muscle aches 0 Joint aches per subject ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	26 Apr 2021 16:21:18
User opened query 'Per CDM: Per previous query response "UPDATED"; however, the update for subject's Diary Dose 2 'Joints Aches' Symptom lasted beyond day 7 post injection is not obvious? Please provide location of update such as the log line number updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:02:04
User closed query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Diary Dose 2 'Joints Aches' Symptom lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:02:04

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:18:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Diary Dose 2 'Joints Aches' Symptom lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:25:53
User opened query 'Per CDM: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Diary Dose 2 'Joints Aches' Symptom lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 11:26:10
User closed query 'Per CDM: Response noted- please update when data is available for Diary Dose 2 Day 8 and Day 9 Fatigue, Headache, Joint Aches and Muscle Aches. Thank you ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 11:26:10
User closed query 'Per CDM: Response noted- please update when data is available for Diary Dose 1 'Swelling'. Thank you ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 11:24:48
User entered 'Yes (Y)' reason for change: New Information	Daisy Langarica (b) (4)	21 Apr 2021 18:41:26
Query 'Per CDM: Response noted- please update when data is available for Diary Dose 2 Day 8 and Day 9 Fatigue, Headache, Joint Aches and Muscle Aches. Thank you ' answered by data change (Site from DM).	(b) (4)	21 Apr 2021 18:41:22
Query 'Per CDM: Response noted- please update when data is available for Diary Dose 1 'Swelling'. Thank you ' answered by data change (Site from DM).	System	21 Apr 2021 18:41:22
DataPoint Un-verified.	Daisy Langarica (b) (4)	21 Apr 2021 18:41:22
Signature has been broken.	(b) (4)	21 Apr 2021 18:41:22
	Daisy Langarica (b) (4)	21 Apr 2021 18:41:22
	(b) (4)	21 Apr 2021 18:41:22

US3262145

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:18:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Daisy Langarica (b) (4)	21 Apr 2021 18:41:22
User opened query 'Per CDM: Response noted-please update when data is available for Diary Dose 2 Day 8 and Day 9 Fatigue, Headache, Joint Aches and Muscle Aches. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 10:20:51
User closed query 'Per CDM :Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Daily Diary Dose 2 Day 8 and Day 9 Fatigue, Headache, Joints and Muscle Aches Symptom lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).		21 Apr 2021 10:20:51
User opened query 'Per CDM: Response noted-please update when data is available for Diary Dose 1 'Swelling'. Thank you ' (Site from DM).		21 Apr 2021 10:19:48
User closed query 'Per CDM :Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Daily Diary 1 Day 8 Swelling Symptom lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).		21 Apr 2021 10:19:48
Query 'Per CDM :Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Daily Diary Dose 2 Day 8 and Day 9 Fatigue, Headache, Joints and Muscle Aches Symptom lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'noted to be added ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	20 Apr 2021 22:31:27

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:18:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per CDM :Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Daily Diary 1 Day 8 Swelling Symptom lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'noted this will be updated ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	20 Apr 2021 22:30:57
User opened query 'Per CDM :Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Daily Diary Dose 2 Day 8 and Day 9 Fatigue, Headache, Joints and Muscle Aches Symptom lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 11:02:02
User opened query 'Per CDM :Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's Daily Diary 1 Day 8 Swelling Symptom lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 10:54:53
User signature succeeded.	Atoya Adams (b) (4) (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:40:37
User entered 'Yes (Y)' reason for change: New Information	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:58:34
User entered 'No (N)'	Alia Bober (b) (4) (b) (4)	07 Oct 2020 14:43:13

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:33:11
Reviewed for Safety.		22 Dec 2020 15:38:59
User entered 'USA-US069-2020-mRNA-1273-P301000003'		22 Dec 2020 15:35:43
User entered 'New'		22 Dec 2020 15:35:43

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:33:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 22:30:54
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 22:30:54
Data point term sent to Coder	System	21 Dec 2020 22:01:01
User entered 'Symptomatic RT-PCR conformed Covid19 infection'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:33:17
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:59:10
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, COVID 19 is not a solicited event for this study. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:28:49
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, COVID 19 is not a solicited event for this study. Please review and update accordingly. Otherwise, clarify.' answered with 'updated ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:25:32
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:23:43
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, COVID 19 is not a solicited event for this study. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 18:09:57
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:33:21
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:33:24
User entered '14 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:33:27
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:59:14
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:25:25
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:48:57
User closed query 'PV Query: Event end date should be the first day that symptoms resolved. Please consider updating event end date to 29 Dec 2020. If not updating, please explain.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 17:47:48
Query 'PV Query: Event end date should be the first day that symptoms resolved. Please consider updating event end date to 29 Dec 2020. If not updating, please explain.' answered with 'updated ' (Site from Safety).	Daisy Langarica (b) (4) (b) (4)	05 Mar 2021 15:51:12
DataPoint Un-verified.	Daisy Langarica (b) (4) (b) (4)	05 Mar 2021 15:50:55
User entered '29 Dec 2020' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	05 Mar 2021 15:50:55
User opened query 'PV Query: Event end date should be the first day that symptoms resolved. Please consider updating event end date to 29 Dec 2020. If not updating, please explain.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:56:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:59:16
DataPoint Un-verified.	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:25:25
User entered '31 Dec 2020' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:25:25
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:33:35
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:33:38
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:59:24
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 19:26:30
User entered empty.	System	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:33:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:34:48
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:34:51
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:34:54
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:34:57
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), (b) (6)	24 Dec 2020 08:53:27
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 'Hospital admission date is captured here, but the discharge date has not occurred yet, and I answered No patient was not admitted to the ICU.' (Site from System).	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:07:58
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	21 Dec 2020 22:00:40
User entered '1'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:35:05
User entered '19 Dec 2020'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
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). 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 'has been faxed - 23 FEB 2021 ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:39:11
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:35:07
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)	14 Jan 2021 20:22:45
User closed query 'Per CDM: Response noted' discharge date has not occurred yet,'. Please update 'Hospital Discharge Date (dd MMM yyyy)' when the data becomes available. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 09:50:27
Query 'Per CDM: Response noted' discharge date has not occurred yet,'. Please update 'Hospital Discharge Date (dd MMM yyyy)' when the data becomes available. Thank you.' answered with 'Data updated as patient was discharged.' (Site from DM).	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:43:22
User entered '25 Dec 2020' reason for change: New Information	Atoya Adams (b) (4) (b) (4)	27 Dec 2020 01:42:48
User opened query 'Per CDM: Response noted' discharge date has not occurred yet,'. Please update 'Hospital Discharge Date (dd MMM yyyy)' when the data becomes available. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:55:32
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:35:12
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:35:14
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:35:17
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:35:20
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:35:26
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:59:22
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).	(b) (4), (b) (6)	18 Feb 2021 20:05:17
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 ' (Site from Safety).	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:24:34
DataPoint Un-verified.	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:23:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:23:43
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:35:23
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).	(b) (4), (b) (6)	29 Dec 2020 19:25:07
User entered 'Not Applicable (NOT APPLICABLE)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:59:25
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).	(b) (4), (b) (6)	18 Feb 2021 20:04:40
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 ' (Site from Safety).	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:24:39
DataPoint Un-verified.	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:23:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:23:43
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:35:28
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).	(b) (4), (b) (6)	14 Jan 2021 20:21:29
User entered 'Not Applicable (NOT APPLICABLE)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:35:33
User entered 'Not Applicable (NOT APPLICABLE)'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

None

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:35:37
User entered '0'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:35:40
User entered '1'	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:49:18
User closed query 'Per DM CLR: RQ: Response noted, however, CHEST AP PORTABLE is a diagnostic procedure. Only therapeutic procedures are accepted for this field to be ticked. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 11:25:31
Query 'Per DM CLR: RQ: Response noted, however, CHEST AP PORTABLE is a diagnostic procedure. Only therapeutic procedures are accepted for this field to be ticked. Update response as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	05 Mar 2021 15:51:21
DataPoint Un-verified.	Daisy Langarica (b) (4) (b) (4)	05 Mar 2021 15:50:55
User entered '0' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	05 Mar 2021 15:50:55
User opened query 'Per DM CLR: RQ: Response noted, however, CHEST AP PORTABLE is a diagnostic procedure. Only therapeutic procedures are accepted for this field to be ticked. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:59:32
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the corresponding treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:34:16
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the corresponding treatment procedure as appropriate. Otherwise, clarify.' answered with 'updated ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:40:29

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the corresponding treatment procedure as appropriate. Otherwise, clarify.' (Site from DM). User entered '1'	(b) (4), (b) (6)	13 Jan 2021 18:10:11
	Atoya Adams (b) (4)	21 Dec 2020 22:00:40
	(b) (4)	

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:59:34
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 20:05:02
User closed query 'Per CDM: As per CCG, Kindly select the drop down and Update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:29:37
Query 'Per CDM: As per CCG, Kindly select the drop down and Update accordingly.' answered with 'updated' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:41:28
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:41:24
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 15:41:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 15:41:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:41:06
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 20:21:57
User opened query 'Per CDM: As per CCG, Kindly select the drop down and Update accordingly.' (Site from DM).		23 Dec 2020 10:10:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 22:00:40
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:59:38
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:06:41
User closed query 'Per DM CLR: SAE Narrative = WAS PLACED ON 3LITERS OF SUPPLEMENTAL OXYGEN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 10:39:13
Query 'Per DM CLR: SAE Narrative = WAS PLACED ON 3LITERS OF SUPPLEMENTAL OXYGEN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'this has been added to con meds ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:21:34
User closed query 'Per DM CLR: SAE Narrative = PORTABLE CHEST XRAY WAS COMPLETED 12/19/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:31:37
Query 'Per DM CLR: SAE Narrative = PORTABLE CHEST XRAY WAS COMPLETED 12/19/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated ' (Site from DM).	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:41:22
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:35:48
User opened query 'Per DM CLR: SAE Narrative = PORTABLE CHEST XRAY WAS COMPLETED 12/19/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		24 Jan 2021 12:22:58
User opened query 'Per DM CLR: SAE Narrative = WAS PLACED ON 3LITERS OF SUPPLEMENTAL OXYGEN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		24 Jan 2021 12:22:52
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' canceled (Site from Safety).		14 Jan 2021 20:26:58

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' canceled (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 20:21:40
User entered 'PATIENT CAME IN DECEMBER 14TH FOR ILLNESS VISIT, AND HIS SYMPTOMS SEEMS TO IMPROVE EXCEPT FOR HIS O2 SAT AND TEMPS. HIS COUGH ACTUALLY WENT FROM MILD TO MODERATE, AND HE DEVELOPED SEVERE SHORTNESS OF BREATH AND DIFFICULTY BREATHING THAT I INSTRUCTED IF THIS HAPPENS GO TO ER. HE WENT ON 12/19/20 AND WAS PLACED ON 3LITERS OF SUPPLEMENTAL OXYGEN. HE ALSO WAS GIVEN EXPERIMENTAL MEDICATION REMDESIVIR THAT WE WILL ENTER ON DECEMBER 24TH AS IF WE DO NOW, THE SYSTEM WILL QUERY. HE IS NOT IN THE ICU BUT IN THE COVID UNIT. I HAVE BEEN SPEAKING TO THE PATIENT AND GETTING VITALS WHILE HE IS IN THE HOSPITAL AND I AM HAVING HIM COLLECT SALIVA SAMPLES WHILE THERE AS WELL AS I INSTRUCTED HIM TO TAKE HIS KIT WITH HIM IN CASE HE NEEDED TO BE HOSPITALIZED. Portable chest xray was completed 12/19/2020 Findings - moderate peripheral groundglass and airspace pacities which correlate with COVID 19 PNEUMONIA NORMAL HEART SIZE WITH ACCENTUATION FUE TO LOW VOLMES NO PLEURAL EFFUSION NO PNEUMOTHORAX NO ACUTE BONY LESION' reason for change: New Information	Daisy Langarica (b) (4)	05 Jan 2021 23:50:32
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 19:25:37
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).	(b) (4), (b) (6)	29 Dec 2020 19:23:56

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Dec 2020 22:06:43
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Dec 2020 22:06:43
User entered 'Patient came in December 14th for illness visit, and his symptoms seems to improve except for his O2 sat and temps. His cough actually went from mild to moderate, and he developed severe Shortness of breath and difficulty breathing that I instructed if this happens go to ER. He went on 12/19/20 and was placed on 3liters of supplemental oxygen. He also was given experimental medication Remdesivir that we will enter on December 24th as if we do now, the system will query. He is not in the ICU but in the covid unit. I have been speaking to the patient and getting vitals while he is in the hospital and I am having him collect saliva samples while there as well as I instructed him to take his kit with him in case he needed to be hospitalized.' reason for change: New Information	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:06:43
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Dec 2020 22:00:40
User entered empty.	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Dec 2020 22:00:40

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalised muscle aches - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:57:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:57:45
Data point term sent to Coder	System	21 Apr 2021 18:35:44
User entered 'whole body muscle aches'	Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User closed query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 11:05:32
Query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:23:45
User entered 'Yes (Y)' reason for change: New Information		22 Apr 2021 17:23:40
User opened query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' (Site from DM).		22 Apr 2021 11:24:00
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '07 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User entered empty.	System	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '13 Sep 2020'	Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User entered empty.	System	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Related (RELATED)'	Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Not Related (NOT RELATED)'	Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'None (NONE)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '1' reason for change: Data Entry Error	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:41:41
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0' reason for change: Data Entry Error	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:41:41
User entered '1'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User entered '0'	System	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18
User entered '0'	System	21 Apr 2021 18:35:31

US3262145

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:11:18

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:58:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:58:11
Data point term sent to Coder	System	21 Apr 2021 18:37:46
User entered 'non migraine headache'	Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User closed query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 11:05:43
Query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:24:26
User entered 'Yes (Y)' reason for change: New Information		22 Apr 2021 17:24:20
User opened query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' (Site from DM).		22 Apr 2021 11:24:12
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '12 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User entered empty.	System	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '13 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01
	(b) (4)	

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User entered empty.	System	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Not Related (NOT RELATED)'	Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Not Related (NOT RELATED)'	Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'None (NONE)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '1'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User entered '0'	System	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56
User entered '0'	System	21 Apr 2021 18:37:01

US3262145

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:56

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
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.	Coder Import (b) (4)	21 Apr 2021 19:58:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 19:58:43
Data point term sent to Coder	System	21 Apr 2021 18:39:49
User entered 'fatigue'	Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User closed query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 11:06:01
Query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:26:32
User entered 'Yes (Y)' reason for change: New Information		22 Apr 2021 17:26:24
User opened query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' (Site from DM).		22 Apr 2021 11:24:22
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '12 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30
	(b) (4)	

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User entered empty.	System	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '13 Sep 2020'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30
	(b) (4)	

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User entered empty.	System	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30
	(b) (4)	

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Not Related (NOT RELATED)'	Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Not Related (NOT RELATED)'	Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'None (NONE)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '1'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User entered '0'	System	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58
User entered '0'	System	21 Apr 2021 18:39:30

US3262145

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:09:58

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site induration, LLT: Injection site induration - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:58:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 19:58:46
Data point term sent to Coder	System	21 Apr 2021 18:40:51
User entered 'hardness at injection site'	Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User closed query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 11:06:08
Query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:27:05
User entered 'Yes (Y)' reason for change: New Information		22 Apr 2021 17:26:50
User opened query 'Per CDM: Note, Was this a Solicited Adverse Reaction?' = NO. However, the event reported is included as one of the solicited AEs per protocol. Please reconcile with CM record and update entry as appropriate. ' (Site from DM).		22 Apr 2021 11:24:35
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '15 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User entered empty.	System	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '16 Aug 2020'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User entered empty.	System	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30
	(b) (4)	

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'No (N)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Related (RELATED)'	Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Not Related (NOT RELATED)'	Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'None (NONE)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30
	(b) (4)	

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '1'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered '0'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:41:03
User entered empty.	(b) (4) Daisy Langarica (b) (4)	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User entered '0'	System	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23
User entered '0'	System	21 Apr 2021 18:40:30

US3262145

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:10:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:18:25

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:03
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:30:59
User closed query 'Please add ConMeds administered during subject hospitalization for COVID SAE (Ceftriaxone and Azithromycin). ' (Site from CRA).	(b) (4)	25 Feb 2021 18:22:39
Query 'Please add ConMeds administered during subject hospitalization for COVID SAE (Ceftriaxone and Azithromycin). ' answered with 'HAS BEEN ADDED THANKS ' (Site from CRA).	Daisy Langarica (b) (4)	23 Feb 2021 17:29:13
User opened query 'Please add ConMeds administered during subject hospitalization for COVID SAE (Ceftriaxone and Azithromycin). ' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 19:13:55
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:40:47
User entered 'Yes (Y)'	Daisy Langarica (b) (4)	10 Aug 2020 14:17:52

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:00:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:00:33
Data point term sent to Coder Coding entries removed.	System Alia Bober (b) (4) (b) (4)	12 Nov 2020 15:59:39 12 Nov 2020 15:59:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:27:13
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:27:13
Data point term sent to Coder User entered 'METOPROLOL'	System Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:43 10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'HYPERTENSION'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '25'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'mg (mg)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'once daily (QD)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User closed query 'Per CDM: As per CCG Page no: 36, Select the route of administration from the drop-down list provided. If route of administration is not listed, select 'Other', and specify in the text box provided and update accordingly.' (Site from DM). Query 'Per CDM: As per CCG Page no: 36, Select the route of administration from the drop-down list provided. If route of administration is not listed, select 'Other', and specify in the text box provided and update accordingly.' answered with 'Oral' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 11:16:21
User closed query 'Data is required. Please complete.' (Site from System). Query 'Data is required. Please complete.' answered by data change (Site from System).	Alia Bober (b) (4) (b) (4)	12 Nov 2020 15:59:39
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 15:59:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 15:59:29
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Alia Bober (b) (4) (b) (4)	12 Nov 2020 15:59:29
User opened query 'Per CDM: As per CCG Page no: 36, Select the route of administration from the drop-down list provided. If route of administration is not listed, select 'Other', and specify in the text box provided and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:20:43
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 14:18:29
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:20:56
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	10 Aug 2020 14:18:29
User entered 'UN UNK 2015'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 15:59:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 15:59:29
User entered 'No (N)' reason for change: Data Entry Error	Alia Bober (b) (4) (b) (4)	12 Nov 2020 15:59:29
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 14:18:29
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:18:29

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:20:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:20:17
Data point term sent to Coder	System	10 Aug 2020 14:19:44
User entered 'ATORVASTATIN'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'DYSLIPIDEMIA'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '10'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'mg (mg)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'once daily (QD)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Oral (ORAL)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 18:40:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'CORRECT AS IS ' (Site from System).	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:29
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	10 Aug 2020 14:19:17
User entered 'un UNK 2010'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:19:17

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:22:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:22:20
Data point term sent to Coder	System	10 Aug 2020 14:20:45
User entered 'BUPROPION'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'anxiety'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '300'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'mg (mg)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'once daily (QD)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Oral (ORAL)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 18:41:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as is ' (Site from System).	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:28
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	10 Aug 2020 14:20:20
User entered 'un UNK 2015'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:20:20

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:22:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:22:22
Data point term sent to Coder	System	10 Aug 2020 14:21:46
User entered 'metformin'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'type 2 diabetes'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '500'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'mg (mg)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'once daily (QD)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Oral (ORAL)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 18:41:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as is ' (Site from System).	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 14:21:10
User entered 'un UNK 2018'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:21:10

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:44:19
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:44:19
Data point term sent to Coder	System	10 Aug 2020 14:22:47
User entered 'aspirin'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User closed query 'Response noted, however no record of "CARDIO PROTECTIVE" on medical history form however HYPERTENSTION is recorded. Kindly review and update else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 09:58:13
Query 'Response noted, however no record of "CARDIO PROTECTIVE" on medical history form however HYPERTENSTION is recorded. Kindly review and update else clarify. ' answered with 'It is not used to treat Hypertension, but is protective against development of coronary artery disease, this term cardio protective. Dr. Adams' (Site from DM).	Atoya Adams (b) (4) (b) (4)	21 Dec 2020 21:47:13
User opened query 'Response noted, however no record of "CARDIO PROTECTIVE" on medical history form however HYPERTENSTION is recorded. Kindly review and update else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:32:35
User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for CARDIOVASCULAR DISEASES etc.). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:32:35
Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for CARDIOVASCULAR DISEASES etc.). Update Con Med eCRF as appropriate.' answered with 'As recorded.' (Site from DM).	Alia Bober (b) (4) (b) (4)	12 Nov 2020 16:00:27
User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for CARDIOVASCULAR DISEASES etc.). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 02:55:22
User entered 'cardio protective'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '81'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'mg (mg)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'once daily (QD)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Oral (ORAL)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 18:41:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as is ' (Site from System).	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:20
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	10 Aug 2020 14:22:12
User entered 'un UNK 2010'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '0'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Yes (Y)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 14:22:12

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
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.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:49:19
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Dec 2020 09:49:19
Data point term sent to Coder	System	24 Dec 2020 22:18:59
Data point term sent to Coder	System	24 Dec 2020 22:17:58
User entered 'Remdesivir'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Severe Symptomatic COVID19' reason for change: New Information	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:18:09
User entered 'COVID19 treatment'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '200'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'mg (mg)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'once daily (QD)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered empty.	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '20 Dec 2020'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '0'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'No (N)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered '24 Dec 2020'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:41:44
User entered 'Yes (Y)'	Atoya Adams (b) (4) (b) (4)	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User entered '1'	System	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User entered '1'	System	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:51:58
User entered '804 (804)'	System	24 Dec 2020 22:17:04

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
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.	Coder Import (b) (4)	18 Mar 2021 09:17:36
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Mar 2021 09:17:36
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 18:22:58
Data point term sent to Coder	System	17 Feb 2021 16:33:59
User entered 'Supplemental Oxygen'	Daisy Langarica (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'Symptomatic RT PCR CONFIRMED COVID19 INFECTION'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '3'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'Other (OTHER)'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'LITERS'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'as needed (PRN)'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered empty.	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'Nasal (NASAL)'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered empty.	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '19 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '0'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 16:55:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 16:55:46
User entered 'No (N)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 16:55:46
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 16:33:23
User entered empty.	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '24 Dec 2020' reason for change: Data Entry Error	Daisy Langarica (b) (4)	23 Feb 2021 16:55:46
User entered empty.	(b) (4) Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User entered empty.	System	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User entered empty.	System	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:02
User entered empty.	System	17 Feb 2021 16:33:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 14:59:57
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 14:59:57
Data point term sent to Coder	System	23 Feb 2021 17:28:59
User entered 'azithromycin'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'SYMPTOMATIC RT PCR CONFIRMED COVID 19 INFECTION'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '500'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'mg (mg)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered empty.	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'unknown (UNKNOWN)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered empty.	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'Intravenous (INTRAVENOUS)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered empty.	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '19 Dec 2019'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '0'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '24 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User entered empty.	System	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User entered empty.	System	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:05
User entered empty.	System	23 Feb 2021 17:28:23

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 13:26:55
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 13:26:55
Data point term sent to Coder	System	23 Feb 2021 17:30:00
User entered 'CEFTRIAXONE'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'SYMPTOMATIC RT PCR CONFIRMED COVID 19 INFECTION'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '2'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'g (g)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered empty.	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'once daily (QD)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered empty.	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'Intravenous (INTRAVENOUS)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered empty.	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '19 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '0'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered '24 Dec 2020'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:23:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:58
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User entered '1'	System	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User entered '1'	System	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:07
User entered '804 (804)'	System	23 Feb 2021 17:29:00

US3262145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:18:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:03
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:10:32
User closed query 'Per ETRTR: According to AE COVID-19, Concomitant procedure was done. Please update this folder or within AE page if no procedure was performed tot he subject, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:37:50
Query 'Per ETRTR: According to AE COVID-19, Concomitant procedure was done. Please update this folder or within AE page if no procedure was performed tot he subject, thanks.' answered with 'updated ' (Site from CRA).	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:28:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Daisy Langarica (b) (4) (b) (4)	17 Feb 2021 15:27:03
User opened query 'Per ETRTR: According to AE COVID-19, Concomitant procedure was done. Please update this folder or within AE page if no procedure was performed tot he subject, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 18:57:44
User entered 'No (N)'	Daisy Langarica (b) (4) (b) (4)	10 Aug 2020 14:24:24

US3262145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:18:25

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:10:32
	(b) (4)	
User entered '19 Dec 2020'	Daisy Langarica (b) (4)	17 Feb 2021 15:27:48
	(b) (4)	

US3262145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:18:25

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:10:32
	(b) (4)	
User entered 'Chest AP Portable'	Daisy Langarica (b) (4)	17 Feb 2021 15:27:48
	(b) (4)	

US3262145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:18:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:10:32
	(b) (4)	
User entered 'Adverse Event (AE)'	Daisy Langarica (b) (4)	17 Feb 2021 15:27:48
	(b) (4)	

US3262145

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:18:25

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	08 Apr 2021 20:10:32
	(b) (4)	
User entered empty.	Daisy Langarica (b) (4)	17 Feb 2021 15:27:48
	(b) (4)	

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'USA-US069-2020-MRNA-1273-P301000003'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Atoya'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Adams'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '2121 E. Flamingo Road'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'las vegas'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'NV'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '89119'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 17:25:30
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
User entered 'US'	(b) (4) System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 17:51:30
User entered '5'	System	24 Feb 2021 15:40:33
User entered '4'	System	18 Feb 2021 19:39:08
User entered '3'	System	06 Jan 2021 20:42:08
Signature has been broken.	System	28 Dec 2020 17:25:40
User entered '2'	System	28 Dec 2020 17:25:40
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
	(b) (4)	
User entered '1'	System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'USA-US069-2020-MRNA-1273-P301000003'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Atoya'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Adams'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '2121 E. Flamingo Road'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'las vegas'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'NV'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '89119'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 17:25:30
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
User entered 'US'	(b) (4) System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 17:51:30
User entered '5'	System	24 Feb 2021 15:40:33
User entered '4'	System	18 Feb 2021 19:39:08
User entered '3'	System	06 Jan 2021 20:42:08
Signature has been broken.	System	28 Dec 2020 17:25:40
User entered '2'	System	28 Dec 2020 17:25:40
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
	(b) (4)	
User entered '1'	System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:18:25

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
User entered '22/Dec/2020 15:41'	(b) (4) System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:18:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 17:25:30
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'USA-US069-2020-MRNA-1273-P301000003'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Atoya'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Adams'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '2121 E. Flamingo Road'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'las vegas'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'NV'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '89119'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 17:25:30
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
User entered 'US'	(b) (4) System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 17:51:30
User entered '5'	System	24 Feb 2021 15:40:33
User entered '4'	System	18 Feb 2021 19:39:08
User entered '3'	System	06 Jan 2021 20:42:08
Signature has been broken.	System	28 Dec 2020 17:25:40
User entered '2'	System	28 Dec 2020 17:25:40
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
	(b) (4)	
User entered '1'	System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:18:25

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:38:12
User entered '28/Dec/2020 17:25'	System	28 Dec 2020 17:25:40

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:18:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:38:12
Reviewed for Safety.		06 Jan 2021 20:41:57
User entered '1'		28 Dec 2020 17:25:40

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'USA-US069-2020-MRNA-1273-P301000003'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Atoya'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Adams'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '2121 E. Flamingo Road'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'las vegas'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'NV'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '89119'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 17:25:30
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
User entered 'US'	(b) (4) System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 17:51:30
User entered '5'	System	24 Feb 2021 15:40:33
User entered '4'	System	18 Feb 2021 19:39:08
User entered '3'	System	06 Jan 2021 20:42:08
Signature has been broken.	System	28 Dec 2020 17:25:40
User entered '2'	System	28 Dec 2020 17:25:40
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
	(b) (4)	
User entered '1'	System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:18:25

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 18:38:12
User entered '06/Jan/2021 20:42'	System	06 Jan 2021 20:42:08

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:18:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:38:49
DataPoint Verified.		16 Feb 2021 18:38:12
User entered '1'		06 Jan 2021 20:42:08

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'USA-US069-2020-MRNA-1273-P301000003'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Atoya'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Adams'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '2121 E. Flamingo Road'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'las vegas'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'NV'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '89119'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 17:25:30
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
User entered 'US'	(b) (4) System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 17:51:30
User entered '5'	System	24 Feb 2021 15:40:33
User entered '4'	System	18 Feb 2021 19:39:08
User entered '3'	System	06 Jan 2021 20:42:08
Signature has been broken.	System	28 Dec 2020 17:25:40
User entered '2'	System	28 Dec 2020 17:25:40
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
	(b) (4)	
User entered '1'	System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:18:25

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:47:07
User entered '18/Feb/2021 14:39'	System	18 Feb 2021 19:39:08

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:18:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:47:10
Reviewed for Safety.		24 Feb 2021 15:40:09
User entered '1'		18 Feb 2021 19:39:08

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'USA-US069-2020-MRNA-1273-P301000003'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Atoya'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Adams'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '2121 E. Flamingo Road'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'las vegas'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'NV'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '89119'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 17:25:30
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
User entered 'US'	(b) (4) System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 17:51:30
User entered '5'	System	24 Feb 2021 15:40:33
User entered '4'	System	18 Feb 2021 19:39:08
User entered '3'	System	06 Jan 2021 20:42:08
Signature has been broken.	System	28 Dec 2020 17:25:40
User entered '2'	System	28 Dec 2020 17:25:40
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
	(b) (4)	
User entered '1'	System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:18:25

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:47:33
User entered '24/Feb/2021 10:40'	System	24 Feb 2021 15:40:33

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:18:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:47:41
Reviewed for Safety.		08 Mar 2021 17:51:17
User entered '1'		24 Feb 2021 15:40:33

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'USA-US069-2020-MRNA-1273-P301000003'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Yes (Y)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'No (N)'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Atoya'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'Adams'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '2121 E. Flamingo Road'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'las vegas'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered 'NV'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:39:38
User entered '89119'	System	22 Dec 2020 15:35:43

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 18:38:12
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 17:25:30
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
User entered 'US'	(b) (4) System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	08 Mar 2021 17:51:30
User entered '5'	System	24 Feb 2021 15:40:33
User entered '4'	System	18 Feb 2021 19:39:08
User entered '3'	System	06 Jan 2021 20:42:08
Signature has been broken.	System	28 Dec 2020 17:25:40
User entered '2'	System	28 Dec 2020 17:25:40
User signature succeeded.	Atoya Adams (b) (4)	27 Dec 2020 01:41:30
	(b) (4)	
User entered '1'	System	22 Dec 2020 15:41:51

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:18:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:47:58
User entered '08/Mar/2021 11:51'	System	08 Mar 2021 17:51:30

US3262145

Folder: SAE USA-US069-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:18:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Atoya Adams (b) (4)	28 Apr 2021 16:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:48:06
User entered 'I'		08 Mar 2021 17:51:30