

US3672255 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:24:23

All time stamps listed in this document are displayed in GMT

US3672255

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 18:04:09

Generated On: 10 Jun 2021 09:24:23

Participant ID

US3672255

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

US3672255

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3672255

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Date of Birth (MMM yyyy)	(b) (6) 1988
Age	32
Age Units	YEARS
Age (Derived)	32
Sex	Female <input checked="" type="radio"/> Male <input 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

US3672255

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3672255

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3672255

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Were any significant conditions reported?

Yes ☒

No ☐

US3672255

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Condition	GENERAL ANXIETY DISORDER
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3672255

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Condition	POST TRAUMATIC STRESS DISORDER
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)	_____

US3672255

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3672255

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Condition	SEVERE OBESTIY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3672255

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3672255

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:17 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:17
Height (<i>xxx.x</i>)	173.6 cm
Weight (<i>xxx.x</i>)	146.4 kg
BMI (<i>xxx.x</i>)	48.57822 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	ND - Not Done
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)	

US3672255

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3672255

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Date of assessment (*dd MMM yyyy*) 21 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

US3672255

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	21 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3672255

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3672255

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 144494

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 ☒

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Height	ND - Not Done
Weight	ND - Not Done

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:17
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	15:27 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 15:27
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3672255

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

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.

US3672255

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 14:56 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 14:56

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

US3672255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 AUG 2020
Collection time (00:00-23:59)	14:52 (24 HR)
Collection date and time (derived)	21 AUG 2020 14:52

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:09	21 AUG 2020 14:09
Nasopharyngeal Swab 2	No		

US3672255

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

21 AUG 2020 15:30

PC Open Date & Time

21 AUG 2020 15:16

PC Close Date & Time

21 AUG 2020 17:46

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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 99.5 °F

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

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

PC Time Stamp	21 AUG 2020 18:43
PC Open Date & Time	21 AUG 2020 18:41
PC Close Date & Time	22 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

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

100.2 °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

22 AUG 2020 13:16

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 15:42

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °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

24 AUG 2020 17:54

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

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	99.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	25 AUG 2020 15:54
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 15:36

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

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	99.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	27 AUG 2020 19:16
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 8

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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:52

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

21 AUG 2020 15:31

PC Open Date & Time

21 AUG 2020 15:16

PC Close Date & Time

21 AUG 2020 17:46

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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

40

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

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

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

21 AUG 2020 18:46

PC Open Date & Time

21 AUG 2020 18:41

PC Close Date & Time

22 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 13:17

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 15:42

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 17:54

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 15:54

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 15:37

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 19:18

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 15:32
PC Open Date & Time	21 AUG 2020 15:16
PC Close Date & Time	21 AUG 2020 17:46

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 18:46
PC Open Date & Time	21 AUG 2020 18:41
PC Close Date & Time	22 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

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 ☒

PRODUCTION RELEASE (v12.003

50 of 3813

EAB) (1725)

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 13:18
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 3813

EAB) (1725)

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 15:43
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 3813

EAB) (1725)

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 17:55
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

56 of 3813

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 15:55
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

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 ☒

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 15:37
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 3813

EAB) (1725)

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 19:21
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 28 AUG 2020 20:52

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 28 AUG 2020 20:52

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 29 AUG 2020 18:49

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

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

30 AUG 2020 13:21

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

31 AUG 2020 16:34

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 SEP 2020 23:59

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

02 SEP 2020 17:28

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

03 SEP 2020 20:54

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

04 SEP 2020 16:16

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

05 SEP 2020 18:54

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

06 SEP 2020 15:02

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 SEP 2020 16:39

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 19

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

08 SEP 2020 12:26

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 20

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

09 SEP 2020 14:19

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 21

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

10 SEP 2020 16:37

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 22

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

11 SEP 2020 13:16

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 23

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

12 SEP 2020 15:46

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 24

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

13 SEP 2020 15:16

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 25

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 17:32

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 26

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

15 SEP 2020 22:22

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

16 SEP 2020 15:15

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 23:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 SEP 2020 20:21

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:04

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 31

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

20 SEP 2020 14:36

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 32

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

21 SEP 2020 15:35

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

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 28 AUG 2020 20:52

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 9

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 29 AUG 2020 18:49

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 10

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 AUG 2020 13:21

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 11

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 31 AUG 2020 16:34

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 12

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 SEP 2020 23:59

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 13

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 02 SEP 2020 17:29

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 14

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 03 SEP 2020 20:55

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 15

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 04 SEP 2020 16:16

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 16

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 05 SEP 2020 18:54

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 17

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 06 SEP 2020 15:02

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 18

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 07 SEP 2020 16:39

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 19

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 08 SEP 2020 12:26

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 20

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 09 SEP 2020 14:19

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 21

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 10 SEP 2020 16:37

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 22

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 11 SEP 2020 13:16

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 23

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 15:46

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 24

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 13 SEP 2020 15:17

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 25

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

14 SEP 2020 17:32

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 26

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 15 SEP 2020 22:22

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 27

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 SEP 2020 15:15

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

28 AUG 2020 20:52

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

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	28 AUG 2020 20:52
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

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	29 AUG 2020 18:50
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 13:21
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 16:34
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 SEP 2020 23:59
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 13
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	02 SEP 2020 17:29
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 20:55
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 15

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

No ☒

Yes ☐

PC Time stamp

04 SEP 2020 16:16

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 18:54
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 17
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	06 SEP 2020 15:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 18
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	07 SEP 2020 16:39
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 19
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	08 SEP 2020 12:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 20
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	09 SEP 2020 14:19
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 21
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	10 SEP 2020 16:37
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 22
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	11 SEP 2020 13:16
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 23
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 15:47
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 24
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 15:17
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 25

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

No ☒

Yes ☐

PC Time stamp

14 SEP 2020 17:32

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 26
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 SEP 2020 22:22
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 15:15
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 20:21
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 21:04
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 14:36
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 SEP 2020 15:35
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3672255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

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)	22 SEP 2020
Time of assessment (00:00-23:59)	15:25 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 15:25
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	16:37 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 16:37
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3672255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

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.

US3672255

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	22 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 16:06 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 16:06

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

US3672255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 SEP 2020
Collection time (00:00-23:59)	15:42 (24 HR)
Collection date and time (derived)	22 SEP 2020 15:42

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:31	22 SEP 2020 15:31
Nasopharyngeal Swab 2	No		

US3672255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 16:39

PC Open Date & Time

22 SEP 2020 16:26

PC Close Date & Time

22 SEP 2020 18:56

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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 99.3 °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	22 SEP 2020 19:53
PC Open Date & Time	22 SEP 2020 19:51
PC Close Date & Time	23 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

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	100.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	23 SEP 2020 14:16
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 15:18

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

25 SEP 2020 13:14

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

26 SEP 2020 18:42

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 17:17

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 17:22

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

22 SEP 2020 16:39

PC Open Date & Time

22 SEP 2020 16:26

PC Close Date & Time

22 SEP 2020 18:56

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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

52

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

22 SEP 2020 19:55

PC Open Date & Time

22 SEP 2020 19:51

PC Close Date & Time

23 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 14:17

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 15:19

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 13:07

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 18:43

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 17:17

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 17:22

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 16:40
PC Open Date & Time	22 SEP 2020 16:26
PC Close Date & Time	22 SEP 2020 18:56

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 19:55
PC Open Date & Time	22 SEP 2020 19:51
PC Close Date & Time	23 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

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 ☒

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 14:17
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

170 of 3813

EAB) (1725)

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 15:19
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

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 ☒

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 13:08
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

174 of 3813

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 18:45
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

176 of 3813

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 17:18
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

178 of 3813

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 17:23
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 29 SEP 2020 13:58

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

29 SEP 2020 13:58

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

30 SEP 2020 16:42

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

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

01 OCT 2020 13:42

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 02 OCT 2020 15:59

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

04 OCT 2020 01:38

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 04 OCT 2020 15:54

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 05 OCT 2020 19:00

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

06 OCT 2020 14:09

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 OCT 2020 18:09

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 OCT 2020 00:03

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

10 OCT 2020 00:07

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 19

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 10 OCT 2020 15:10

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

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 29 SEP 2020 13:58

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 9

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 SEP 2020 16:43

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 10

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 OCT 2020 13:42

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 11

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 02 OCT 2020 16:00

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 12

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 04 OCT 2020 01:38

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 13

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 04 OCT 2020 15:54

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 14

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 OCT 2020 19:00

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 15

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 06 OCT 2020 14:09

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 16

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 07 OCT 2020 18:09

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 17

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 OCT 2020 00:03

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 18

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 10 OCT 2020 00:07

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 19

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 10 OCT 2020 15:10

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 20

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 11 OCT 2020 23:59

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 21

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 OCT 2020 16:44

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 22

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 13 OCT 2020 16:16

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 23

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 14 OCT 2020 12:07

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 24

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 15 OCT 2020 15:11

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 25

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 OCT 2020 12:58

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 26

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 OCT 2020 16:21

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 27

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 OCT 2020 14:23

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 28

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 OCT 2020 00:00

PC Open Date & Time 19 OCT 2020 12:00

PC Close Date & Time 20 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 29

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 20 OCT 2020 12:59

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 30

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 21 OCT 2020 21:33

PC Open Date & Time 21 OCT 2020 12:00

PC Close Date & Time 22 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 31

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 OCT 2020 18:21

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 32

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 23 OCT 2020 15:52

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 33

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 24 OCT 2020 21:21

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 34

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 25 OCT 2020 16:49

PC Open Date & Time 25 OCT 2020 12:00

PC Close Date & Time 26 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 35

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 26 OCT 2020 15:18

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 36

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 27 OCT 2020 13:14

PC Open Date & Time 27 OCT 2020 12:00

PC Close Date & Time 28 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 37

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 28 OCT 2020 13:14

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 38

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 29 OCT 2020 12:11

PC Open Date & Time 29 OCT 2020 12:00

PC Close Date & Time 30 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 39

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 30 OCT 2020 19:41

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 40

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 31 OCT 2020 12:08

PC Open Date & Time 31 OCT 2020 12:00

PC Close Date & Time 01 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 41

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 01 NOV 2020 23:59

PC Open Date & Time 01 NOV 2020 12:00

PC Close Date & Time 02 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 42

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 02 NOV 2020 12:32

PC Open Date & Time 02 NOV 2020 12:00

PC Close Date & Time 03 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 43

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 03 NOV 2020 12:14

PC Open Date & Time 03 NOV 2020 12:00

PC Close Date & Time 04 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 44

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

04 NOV 2020 14:52

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 45

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 05 NOV 2020 14:12

PC Open Date & Time 05 NOV 2020 12:00

PC Close Date & Time 06 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 46

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 06 NOV 2020 23:59

PC Open Date & Time 06 NOV 2020 12:00

PC Close Date & Time 07 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 47

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 07 NOV 2020 23:59

PC Open Date & Time 07 NOV 2020 12:00

PC Close Date & Time 08 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 48

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 09 NOV 2020 00:25

PC Open Date & Time 08 NOV 2020 12:00

PC Close Date & Time 09 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 49

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 09 NOV 2020 13:13

PC Open Date & Time 09 NOV 2020 12:00

PC Close Date & Time 10 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 50

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 10 NOV 2020 23:59

PC Open Date & Time 10 NOV 2020 12:00

PC Close Date & Time 11 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 51

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 NOV 2020 00:31

PC Open Date & Time 11 NOV 2020 12:00

PC Close Date & Time 12 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 52

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 NOV 2020 12:49

PC Open Date & Time 12 NOV 2020 12:00

PC Close Date & Time 13 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 53

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 13 NOV 2020 12:00

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 54

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 14 NOV 2020 18:14

PC Open Date & Time 14 NOV 2020 12:00

PC Close Date & Time 15 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 55

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 15 NOV 2020 17:05

PC Open Date & Time 15 NOV 2020 12:00

PC Close Date & Time 16 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 56

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 16 NOV 2020 12:12

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 57

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 NOV 2020 12:00

PC Open Date & Time 17 NOV 2020 12:00

PC Close Date & Time 18 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 58

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 NOV 2020 12:31

PC Open Date & Time 18 NOV 2020 12:00

PC Close Date & Time 19 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 59

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 19 NOV 2020 12:05

PC Open Date & Time 19 NOV 2020 12:00

PC Close Date & Time 20 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 60

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

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 20 NOV 2020 21:03

PC Open Date & Time 20 NOV 2020 12:00

PC Close Date & Time 21 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 61

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

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 62

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

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

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	29 SEP 2020 13:58
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

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	30 SEP 2020 16:43
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 13:42
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 16:00
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 OCT 2020 01:38
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

04 OCT 2020 15:54

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 19:00
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 15

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

No ☒

Yes ☐

PC Time stamp

06 OCT 2020 14:09

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 18:09
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 17
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	09 OCT 2020 00:04
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 18
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	10 OCT 2020 00:07
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 19
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	10 OCT 2020 15:10
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 20
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	11 OCT 2020 23:59
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 21
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 OCT 2020 16:44
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 22
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 OCT 2020 16:17
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 23

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

No ☒

Yes ☐

PC Time stamp

14 OCT 2020 12:07

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 24
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 OCT 2020 15:11
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 25
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 OCT 2020 12:58
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 OCT 2020 16:21
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 14:23
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 00:01
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 12:59
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 21:34
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 18:21
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 15:52
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 33

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

No ☒

Yes ☐

PC Time stamp

24 OCT 2020 21:21

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 34
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	25 OCT 2020 16:49
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 35
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	26 OCT 2020 15:18
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 36
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	27 OCT 2020 13:14
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 37

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

No ☒

Yes ☐

PC Time stamp

28 OCT 2020 13:14

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 38
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	29 OCT 2020 12:11
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 39
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	30 OCT 2020 19:41
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 40
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	31 OCT 2020 12:08
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 41
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	01 NOV 2020 23:59
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 42
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	02 NOV 2020 12:32
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 43
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	03 NOV 2020 12:14
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 44
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	04 NOV 2020 14:52
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 45
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	05 NOV 2020 14:12
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 46
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	06 NOV 2020 23:59
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 47
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	07 NOV 2020 23:59
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 48
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	09 NOV 2020 00:25
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 49
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	09 NOV 2020 13:13
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 50
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	10 NOV 2020 23:59
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 51
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 NOV 2020 00:31
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 52
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 NOV 2020 12:49
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 53
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 NOV 2020 12:00
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 54
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	14 NOV 2020 18:14
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 55

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

No ☒

Yes ☐

PC Time stamp

15 NOV 2020 17:05

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 56

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

No ☐

Yes ☒

PC Time stamp

16 NOV 2020 17:49

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 57

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

No ☒

Yes ☐

PC Time stamp

17 NOV 2020 12:00

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 58

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

No ☒

Yes ☐

PC Time stamp

18 NOV 2020 12:31

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 59

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

No ☒

Yes ☐

PC Time stamp

19 NOV 2020 12:05

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 60
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 NOV 2020 21:03
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 61
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 62
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3672255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:53

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	15:22 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 15:22
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

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.

US3672255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	15:33 (24 HR)
Collection date and time (derived)	19 OCT 2020 15:33

US3672255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:06:55

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 OCT 2020 00:36:48
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 00:01:35

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 14:53:04

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 NOV 2020 12:32:15
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 NOV 2020 16:04:46
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 NOV 2020 00:11:08
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 00:01:36

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 02:37:24

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 00:51:31

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 DEC 2020 00:36:56
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

03 JAN 2021 19:39:52

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

10 JAN 2021 00:03:13

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 00:05:01
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 12:35:07
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

09 FEB 2021 22:51:57

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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	14 FEB 2021 19:05:45
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 07:47:12

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

01 MAR 2021 01:06:10

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 00:23:42

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

14 MAR 2021 10:12:26

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 00:36:52

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 MAR 2021 17:41:10
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 22:36:39

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 16:01:52

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 05:57:46

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:30:07

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 09:07:12

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	19 AUG 2021 23:59
---	-------------------

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

Patient Cloud Open Date & Time	21 NOV 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	25 NOV 2021 23:59
---	-------------------

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3672255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:24:23

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		01 MAR 2021 01:06:17

US3672255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:04:14

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:04:14

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:04:14

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:04:13

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:04:14

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:04:14

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:04:14

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:04:14

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 14:31:54

Generated On: 10 Jun 2021 09:24:23

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT4

US3672255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3672255

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

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.

US3672255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3672255

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 14:31:54

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 14:31:54

Generated On: 10 Jun 2021 09:24:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672255

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 14:31:54

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672255

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Date of Contact	28 DEC 2020
Time of Contact	14:00
Date and Time of Contact (derived)	28 DEC 2020 14:00
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

517 of 3813

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	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"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

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"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input 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 type="checkbox"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

521 of 3813

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

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"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input 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 type="checkbox"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

525 of 3813

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

526 of 3813

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

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"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input 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 type="checkbox"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

529 of 3813

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

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"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	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	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input 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 type="checkbox"/>
	Mild	<input checked="" 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"/>
PRODUCTION RELEASE (v12.003		533 of 3813
EAB) (1725)		

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

534 of 3813

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

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"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	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	98 %	
O2 Saturation Units	%	
Temperature	99.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

537 of 3813

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

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"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	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	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

541 of 3813

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

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"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	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	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

545 of 3813

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

Date of Visit	28 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	28 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Mar 2021 18:04:13

Generated On: 10 Jun 2021 09:24:23

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 DEC 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3672255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:04:13

Generated On: 10 Jun 2021 09:24:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 18:04:13

Generated On: 10 Jun 2021 09:24:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 14:05
Height (xxx.x)	173.60 cm
Weight (xxx.x)	149.3 kg
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672255

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:04:13

Generated On: 10 Jun 2021 09:24:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 DEC 2020

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

US3672255

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Mar 2021 18:04:13

Generated On: 10 Jun 2021 09:24:23

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 DEC 2020

US3672255

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:04:13

Generated On: 10 Jun 2021 09:24:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3672255

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:15:52

Generated On: 10 Jun 2021 09:24:23

Date of updated informed consent (*dd MMM yyyy*) 02 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 2 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3672255

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:04:13

Generated On: 10 Jun 2021 09:24:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00-23:59)	13:23 (24 HR)
Collection date and time (derived)	2 FEB 2021 13:23

US3672255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 18:04:13

Generated On: 10 Jun 2021 09:24:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 FEB 2021
Collection time (00:00 - 23:59)	13:18
Collection Date and Time (derived)	2 FEB 2021 13:18

US3672255

Folder: Unscheduled (1)

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:24:23

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3672255

Folder: Unscheduled (2)

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:24:23

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3672255

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 18:04:11

Generated On: 10 Jun 2021 09:24:23

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

AEID

Adverse event

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)

22 SEP 2020

Start time (00:00-23:59)

16:40 (24 HR)

AE start date and time (derived)

22 SEP 2020 16:40

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

561 of 3813

EAB) (1725)

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

AEID

Adverse event

INTERMITTENT FATIGUE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 SEP 2020

Start time (00:00-23:59)

16:40 (24 HR)

AE start date and time (derived)

22 SEP 2020 16:40

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 OCT 2020

End time (00:00-23:59)

0:03 (24 HR)

AE End Date and Time (derived)

9 OCT 2020 0:03

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

563 of 3813

EAB) (1725)

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

AEID	
Adverse event	INTERMITTENT JOINT ACHE (BILATERAL ANKLES)
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)	22 SEP 2020
Start time (00:00-23:59)	16:40 (24 HR)
AE start date and time (derived)	22 SEP 2020 16:40
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

565 of 3813

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

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 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 Withdrawn <input type="radio"/> Not Applicable <input 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 checked="" type="radio"/> Recovered/Resolved <input 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)	

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

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)	21 AUG 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)	21 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

567 of 3813

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

AEID

Adverse event

GENERALIZED JOINT 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)

22 AUG 2020

Start time (00:00-23:59)

13:18 (24 HR)

AE start date and time (derived)

22 AUG 2020 13:18

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 SEP 2020

End time (00:00-23:59)

22:22 (24 HR)

AE End Date and Time (derived)

15 SEP 2020 22:22

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

569 of 3813

EAB) (1725)

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

AEID

Adverse event

UPPER RESPIRATORY
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)

24 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)

31 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

571 of 3813

EAB) (1725)

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

AEID

Adverse event

RIGHT AXILLA PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

573 of 3813

EAB) (1725)

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

AEID

Adverse event

RIGHT GROIN PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

575 of 3813

EAB) (1725)

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

AEID	USA-US116-2021-MRNA-1273-P30 1000011
Adverse event	SUICIDAL IDEATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 MAR 2021
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)	2 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	2 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

577 of 3813

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

WE HAVE BEEN TRYING TO REACH PATIENT REGARDING ALERTS RELATED TO COVID EXPOSURE AND HAD BEEN UNABLE. FINALLY PATIENT RETURNED OUR CALL TODAY TO STATE THEY HAD BEEN UNABLE TO RESPOND DUE TO HOSPITALIZATION FOR SUICIDAL IDEATION. THEIR PSYCH MEDS WERE DISCONTINUED IN THE HOSPITAL AND A NEW REGIMEN BEGUN.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

AEID	
Adverse event	WORSENING DEPRESSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	3 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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	

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 12 Apr 2021 20:44:16

Generated On: 10 Jun 2021 09:24:23

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 18:04:12

Generated On: 10 Jun 2021 09:24:23

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

Yes ☒

No ☐

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

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication DIAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

583 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication AMITRIPTYLINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

585 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication PROZAC

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

587 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

589 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 AUG 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"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

591 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 27 AUG 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"/>	

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

BID

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

593 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication JOINT ACHES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

595 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication HEARTBURN

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

597 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication GROIN PAIN, RIGHT SIDE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

599 of 3813

EAB) (1725)

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication DAYQUIL (INGREDIENTS UNKNOWN)

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY 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)

601 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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 type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication NYQUIL (INGREDIENTS UNKNOWN)

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY 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)

603 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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 type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication INTERMITTENT JOINT ACHES

Dose per administration 3600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

605 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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)	28 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication PAXIL

Prophylaxis Yes ☐
No ☒

Indication WORSENING DEPRESSION;
SUICIDAL IDEATION

Dose per administration 40

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)

607 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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 type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication ZESTRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

609 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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)	28 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

611 of 3813

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 15:15:47

Generated On: 10 Jun 2021 09:24:23

	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)	28 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3672255

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:42:15

Generated On: 10 Jun 2021 09:24:23

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3672255

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:24:23

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

US3672255

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:24:23

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 ☐

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 18:36:01

Generated On: 10 Jun 2021 09:24:23

SAEID	USA-US116-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	4920 O'HEAR AVE, SUITE 101
Site Address: City	N CHARLESTON
Site Address: State	
Site Address: Postal Code	29405
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 18:36:01

Generated On: 10 Jun 2021 09:24:23

SAEID	USA-US116-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	4920 O'HEAR AVE, SUITE 101
Site Address: City	N CHARLESTON
Site Address: State	
Site Address: Postal Code	29405
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/APR/2021 12:39
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

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 18:36:01

Generated On: 10 Jun 2021 09:24:23

SAEID	USA-US116-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	4920 O'HEAR AVE, SUITE 101
Site Address: City	N CHARLESTON
Site Address: State	
Site Address: Postal Code	29405
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	12/APR/2021 09:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3672255 (Prod: Coastal Carolina Research Center)

US3672255

Form: Participant Creation

Generated On: 10 Jun 2021 09:24:23

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'US3672255'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:14:20

US3672255

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 19:24:41
	(b) (4), (b) (6)	

US3672255

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:14:21

US3672255

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 19:24:41

US3672255

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'SCRN'	System	21 Aug 2020 19:24:41

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered (b) (6) 1988'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:14:23

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '32'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'YEARS'	System	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '32'	System	21 Aug 2020 19:25:10

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:23

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:02:37

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '21 Aug 2020'	(b) (4)	21 Aug 2020 19:25:10
	(b) (4), (b) (6)	

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'Aug 2020'	System	21 Aug 2020 19:25:10

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '2020'	System	21 Aug 2020 19:25:10

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Amendment 2 (2)'	(b) (4)	21 Aug 2020 19:25:10
	(b) (4), (b) (6)	

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 19:25:10
	(b) (4), (b) (6)	

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4)	21 Aug 2020 19:25:10
	(b) (4), (b) (6)	

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4)	21 Aug 2020 19:25:10
	(b) (4), (b) (6)	

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4)	21 Aug 2020 19:25:10
	(b) (4), (b) (6)	

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:14:21

US3672255

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'I'	System	21 Aug 2020 19:25:43

US3672255

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 19:25:43
	(b) (4), (b) (6)	

US3672255

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:24:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:04:32

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Generalised anxiety disorder, LLT: Generalized anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:06:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:06:35
Data point term sent to Coder	System	25 Aug 2020 17:05:18
User entered 'GENERAL ANXIETY DISORDER'	(b) (4), (b) (6)	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'UN UNK 2014'	(b) (4), (b) (6)	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'Jan 2014'	System	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '2014'	System	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:23

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	25 Aug 2020 17:05:04

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User closed query 'Per MM: please expand the abbreviation.' (Site from DM).	(b) (4)	28 Oct 2020 18:43:08
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:56:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Oct 2020 19:56:44
Query 'Per MM: please expand the abbreviation.' answered with 'acronym defined.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 19:56:11
Data point term sent to Coder	System	21 Oct 2020 19:56:10
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 19:55:53
User entered 'Post traumatic stress disorder' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:55:53
User opened query 'Per MM: please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:47:03
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:07:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	25 Aug 2020 17:07:35
Data point term sent to Coder	System	25 Aug 2020 17:06:19
User entered 'PTSD'	(b) (4), (b) (6)	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'Jan 2018'	System	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '2018'	System	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:23

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	25 Aug 2020 17:05:27

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:07:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:07:34
Data point term sent to Coder	System	25 Aug 2020 17:06:20
User entered 'DEPRESSION'	(b) (4), (b) (6)	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'UN UNK 2000'	(b) (4), (b) (6)	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'Jan 2000'	System	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '2000'	System	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:23

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	25 Aug 2020 17:05:50

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 05:56:22
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 05:56:22
Data point term sent to Coder	System	23 Oct 2020 15:14:12
User entered 'severe obestiy'	(b) (4), (b) (6)	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'Jan 2017'	System	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '2017'	System	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:23

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	23 Oct 2020 15:14:05

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 19:48:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 19:48:23
Data point term sent to Coder	System	28 Dec 2020 19:47:27
User entered 'heartburn'	Patty Howenstine (b) (4)	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'un UNK 2017'	Patty Howenstine (b) (4)	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	Patty Howenstine (b) (4)	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'Jan 2017'	System	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '2017'	System	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:23

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	28 Dec 2020 19:47:03

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '14:17'	(b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '21 Aug 2020 14:17'	System	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '173.6' cm	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:07:40
DataPoint set to visible.	System	21 Aug 2020 19:25:43

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '146.4' kg	(b) (4), (b) (6)	25 Aug 2020 17:07:40
DataPoint set to visible.	System	21 Aug 2020 19:25:43

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User closed query 'Per CDM : Requery: Response noted, however Severe Obesity has not been updated in Medical History. Kindly consider to update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:53:06
Query 'Per CDM : Requery: Response noted, however Severe Obesity has not been updated in Medical History. Kindly consider to update accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:15:38
User opened query 'Per CDM : Requery: Response noted, however Severe Obesity has not been updated in Medical History. Kindly consider to update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:41:49
User closed query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:41:17
Query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' answered with 'CONFIRMED BMI CORRECT. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 16:28:59
Amendment Manager: User entered '48.57822'	System	17 Sep 2020 00:18:54
User opened query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 19:08:34
User entered '48.6'	System	25 Aug 2020 17:07:40
DataPoint set to visible.	System	21 Aug 2020 19:25:43

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'kg/m2'	System	25 Aug 2020 17:07:40
DataPoint set to visible.	System	21 Aug 2020 19:25:43

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User closed query 'Per CDM: Please consider to keep the Route of measurement field as "Blank", since Temperature is recorded as ND and kindly update accordingly. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please consider to keep the Route of measurement field as "Blank", since Temperature is recorded as ND and kindly update accordingly. Thank you.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:41:26
Query 'Per CDM: Please consider to keep the Route of measurement field as "Blank", since Temperature is recorded as ND and kindly update accordingly. Thank you.'	(b) (4), (b) (6)	27 Oct 2020 19:48:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:48:17
User opened query 'Per CDM: Please consider to keep the Route of measurement field as "Blank", since Temperature is recorded as ND and kindly update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:53:52
User entered 'Other (Other)'	(b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'bpm'	System	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'breaths/min'	System	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'mmHg'	System	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'mmHg'	System	25 Aug 2020 17:07:40

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38

US3672255

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38

US3672255

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:07:57

US3672255

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '21 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 17:07:57

US3672255

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:08:34

US3672255

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:24:23

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:08:34

US3672255

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:24:23

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:08:34

US3672255

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:24:23

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:08:34

US3672255

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:08:34

US3672255

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:24:23

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:08:34

US3672255

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:08:34

US3672255

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:24:23

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:08:34

US3672255

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:09:08

US3672255

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '21 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 17:09:08

US3672255

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Urine (URINE)'	(b) (4), (b) (6)	25 Aug 2020 17:09:08

US3672255

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	25 Aug 2020 17:09:08

US3672255

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:09:08

US3672255

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:09:08

US3672255

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:09:08

US3672255

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	25 Aug 2020 17:09:08

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

[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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

[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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

[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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:10:45

US3672255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:11:03

US3672255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '21 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 17:11:03

US3672255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:11:03

US3672255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'VISIT1'	System	25 Aug 2020 17:11:03

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:40:18

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '144494'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:40:18

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:40:18

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:23

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)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:16:47
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'CONFIRMED ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 16:13:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 16:13:28
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 18:59:40
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	31 Aug 2020 19:25:48
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 17:17:00
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:00

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:23

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)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	31 Aug 2020 19:25:50
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 17:17:00
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:00

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Per CDM: Please ensure the actual condition is recorded on the Medical History form' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:13:44
Query 'Per CDM: Please ensure the actual condition is recorded on the Medical History form' answered with 'CONFIRMED ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 16:13:23
User opened query 'Per CDM: Please ensure the actual condition is recorded on the Medical History form' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 19:28:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:17:00

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4)	
	(b) (4), (b) (6)	31 Aug 2020 19:25:52
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 17:17:00
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:00

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:23

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	31 Aug 2020 19:25:55
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 17:17:00
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:00

US3672255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:23

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 16:14:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 16:14:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 16:14:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 16:13:28
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 16:13:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:35
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:07:46

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User entered '173.6' cm	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User entered '146.4' kg	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User entered '173.6' cm	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User entered '146.4' kg	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:19:30
User entered '21 Aug 2020' reason for change: Data Entry Error	System	25 Aug 2020 17:19:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:19:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:19:30
User entered '14:17' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '21 Aug 2020 14:17'	System	25 Aug 2020 17:19:30
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:19:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:19:30
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:19:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).		25 Aug 2020 17:19:36
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:36
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:19:30
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:19:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:19:30
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'bpm'	System	25 Aug 2020 17:19:30
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:19:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:19:30
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'breaths/min'	System	25 Aug 2020 17:19:30
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:19:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:19:30
User entered '128' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	25 Aug 2020 17:19:30
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:19:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:19:30
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	25 Aug 2020 17:19:30
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User entered '173.6' cm	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:19:30
User entered '146.4' kg	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:20:38
User entered '21 Aug 2020' reason for change: Data Entry Error	System	25 Aug 2020 17:20:38
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:20:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).		25 Aug 2020 17:20:38
User entered '15:27' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:20:38
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '21 Aug 2020 15:27'	System	25 Aug 2020 17:20:38
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:20:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).		25 Aug 2020 17:20:38
User entered '99.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:20:38
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:20:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		25 Aug 2020 17:20:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:20:43
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:20:38
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:20:10
User entered '85' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:20:10
User opened query 'Data is required. Please provide.' (Site from System).		25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'bpm'	System	25 Aug 2020 17:20:10
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:20:10
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:20:10
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'breaths/min'	System	25 Aug 2020 17:20:10
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:20:10
User entered '119' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:20:10
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	25 Aug 2020 17:20:10
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 17:20:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	25 Aug 2020 17:20:10
User entered '85' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 17:20:10
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Aug 2020 17:17:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	25 Aug 2020 17:20:10
User entered empty.	System	25 Aug 2020 17:17:49

US3672255

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:21:13

US3672255

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:21:13

US3672255

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User closed query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:05:44
Query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 21:41:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:41:47
User opened query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 05:23:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:21:37

US3672255

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:41:47
User entered '21 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 17:21:37

US3672255

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:41:47
User entered 'Urine (URINE)'	(b) (4), (b) (6)	25 Aug 2020 17:21:37

US3672255

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:41:47
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	25 Aug 2020 17:21:37

US3672255

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 17:21:37

US3672255

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:21:37

US3672255

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:21:37

US3672255

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered empty.	System	25 Aug 2020 17:21:37

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4)	21 Aug 2020 19:26:56
	(b) (4), (b) (6)	

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4)	21 Aug 2020 19:26:56
	(b) (4), (b) (6)	

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

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)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4)	21 Aug 2020 19:26:56
	(b) (4), (b) (6)	

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 19:26:56

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '21 Aug 2020'	(b) (4)	21 Aug 2020 19:26:56
	(b) (4), (b) (6)	

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '14:56'	(b) (4)	21 Aug 2020 19:26:56
	(b) (4), (b) (6)	

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '21 Aug 2020 14:56'	System	21 Aug 2020 19:26:56

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Left Arm (LEFT ARM)'	(b) (4)	21 Aug 2020 19:26:56
	(b) (4), (b) (6)	

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'ONCE'	System	21 Aug 2020 19:26:56

US3672255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 19:26:56

US3672255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:21:58

US3672255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:21:58

US3672255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '14:52'	(b) (4), (b) (6)	25 Aug 2020 17:21:58

US3672255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '21 Aug 2020 14:52'	System	25 Aug 2020 17:21:58

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '21 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 17:22:21

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	25 Aug 2020 17:22:21

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:22:21

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '14:09'	(b) (4), (b) (6)	25 Aug 2020 17:22:21

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '21 Aug 2020 14:09'	System	25 Aug 2020 17:22:21

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	25 Aug 2020 17:22:21

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:22:21

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:22:21

US3672255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered empty.	System	25 Aug 2020 17:22:21

US3672255

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:22:28

US3672255

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	25 Aug 2020 17:22:28

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:30:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '464d9e86-223a-4db8-850f-2174d999c068'	System	21 Aug 2020 19:31:00
User entered 'Yes (Y)'	System	21 Aug 2020 19:31:00

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:30:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '464d9e86-223a-4db8-850f-2174d999c068'	System	21 Aug 2020 19:31:00
User entered '99.0'	System	21 Aug 2020 19:31:00

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:30:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '464d9e86-223a-4db8-850f-2174d999c068'	System	21 Aug 2020 19:31:00
User entered 'No (N)'	System	21 Aug 2020 19:31:00

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:30:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '464d9e86-223a-4db8-850f-2174d999c068'	System	21 Aug 2020 19:31:00
User entered '21 Aug 2020 15:30'	System	21 Aug 2020 19:31:00

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Aug 2020 15:16'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Aug 2020 17:46'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:43:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '748b2bad-0e69-4c4b-9afb-ff4af829bcd0'	System	21 Aug 2020 22:43:49
User entered 'Yes (Y)'	System	21 Aug 2020 22:43:49

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:43:37', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '748b2bad-0e69-4c4b-9afb-ff4af829bcd0'	System	21 Aug 2020 22:43:49
User entered '99.5'	System	21 Aug 2020 22:43:49

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:43:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '748b2bad-0e69-4c4b-9afb-ff4af829bcd0'	System	21 Aug 2020 22:43:49
User entered 'No (N)'	System	21 Aug 2020 22:43:49

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:43:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '748b2bad-0e69-4c4b-9afb-ff4af829bcd0'	System	21 Aug 2020 22:43:49
User entered '21 Aug 2020 18:43'	System	21 Aug 2020 22:43:49

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Aug 2020 18:41'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 2'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:16:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2d59541d-49dd-4f09-a12e-f7bfbe3d130c'	System	22 Aug 2020 17:16:42
User entered 'Yes (Y)'	System	22 Aug 2020 17:16:42

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:16:32', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2d59541d-49dd-4f09-a12e-f7bfbe3d130c' User entered '100.2'	System	22 Aug 2020 17:16:42
	System	22 Aug 2020 17:16:42

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:16:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2d59541d-49dd-4f09-a12e-f7bfbe3d130c'	System	22 Aug 2020 17:16:42
User entered 'No (N)'	System	22 Aug 2020 17:16:42

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:16:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2d59541d-49dd-4f09-a12e-f7bfbe3d130c'	System	22 Aug 2020 17:16:42
User entered '22 Aug 2020 13:16'	System	22 Aug 2020 17:16:42

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 3'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'edee47ce-f138-44da-93a9-3d6b6ac9d9fd'	System	23 Aug 2020 19:42:31
User entered 'Yes (Y)'	System	23 Aug 2020 19:42:31

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'edee47ce-f138-44da-93a9-3d6b6ac9d9fd'	System	23 Aug 2020 19:42:31
User entered '99.4'	System	23 Aug 2020 19:42:31

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'edee47ce-f138-44da-93a9-3d6b6ac9d9fd'	System	23 Aug 2020 19:42:31
User entered 'No (N)'	System	23 Aug 2020 19:42:31

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'edee47ce-f138-44da-93a9-3d6b6ac9d9fd'	System	23 Aug 2020 19:42:31
User entered '23 Aug 2020 15:42'	System	23 Aug 2020 19:42:31

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 4'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:09', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5fbdcfb-50ff-4912-8ac1-cf2eb9476cab'	System	24 Aug 2020 21:54:22
User entered 'Yes (Y)'	System	24 Aug 2020 21:54:22

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5fbdcfb-50ff-4912-8ac1-cf2eb9476cab'	System	24 Aug 2020 21:54:22
User entered '99.1'	System	24 Aug 2020 21:54:22

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5fbdcfb-50ff-4912-8ac1-cf2eb9476cab'	System	24 Aug 2020 21:54:22
User entered 'No (N)'	System	24 Aug 2020 21:54:22

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5fbdcfb-50ff-4912-8ac1-cf2eb9476cab'	System	24 Aug 2020 21:54:22
User entered '24 Aug 2020 17:54'	System	24 Aug 2020 21:54:22

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 5'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e22ebcf3-83c4-4ebd-8ae7-32075c50a563'	System	25 Aug 2020 19:54:37
User entered 'Yes (Y)'	System	25 Aug 2020 19:54:37

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e22ebcf3-83c4-4ebd-8ae7-32075c50a563'	System	25 Aug 2020 19:54:37
User entered '99.6'	System	25 Aug 2020 19:54:37

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e22ebcf3-83c4-4ebd-8ae7-32075c50a563'	System	25 Aug 2020 19:54:37
User entered 'Yes (Y)'	System	25 Aug 2020 19:54:37

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'conmed treatment recorded in conmed chart.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 09:14:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 19:49:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e22ebcf3-83c4-4ebd-8ae7-32075c50a563'	System	25 Aug 2020 19:54:37
User entered '1'	System	25 Aug 2020 19:54:37

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e22ebcf3-83c4-4ebd-8ae7-32075c50a563'	System	25 Aug 2020 19:54:37
User entered '0'	System	25 Aug 2020 19:54:37

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:34', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e22ebcf3-83c4-4ebd-8ae7-32075c50a563'	System	25 Aug 2020 19:54:37
User entered '25 Aug 2020 15:54'	System	25 Aug 2020 19:54:37

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 6'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:36:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5bf4be2-4d78-4ac1-b3e1-53022c1f07df'	System	26 Aug 2020 19:36:51
User entered 'Yes (Y)'	System	26 Aug 2020 19:36:51

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:36:39', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5bf4be2-4d78-4ac1-b3e1-53022c1f07df'	System	26 Aug 2020 19:36:51
User entered '98.6'	System	26 Aug 2020 19:36:51

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:36:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5bf4be2-4d78-4ac1-b3e1-53022c1f07df'	System	26 Aug 2020 19:36:51
User entered 'No (N)'	System	26 Aug 2020 19:36:51

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:36:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5bf4be2-4d78-4ac1-b3e1-53022c1f07df'	System	26 Aug 2020 19:36:51
User entered '26 Aug 2020 15:36'	System	26 Aug 2020 19:36:51

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 7'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:16:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03329568-c066-4d11-a08d-a7639ed21f07'	System	27 Aug 2020 23:17:04
User entered 'Yes (Y)'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:16:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03329568-c066-4d11-a08d-a7639ed21f07'	System	27 Aug 2020 23:17:04
User entered '99.4'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:16:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03329568-c066-4d11-a08d-a7639ed21f07'	System	27 Aug 2020 23:17:04
User entered 'Yes (Y)'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication taken for headache relief recorded in conmed chart.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 09:16:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 19:50:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:16:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03329568-c066-4d11-a08d-a7639ed21f07'	System	27 Aug 2020 23:17:04
User entered '1'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:16:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03329568-c066-4d11-a08d-a7639ed21f07'	System	27 Aug 2020 23:17:04
User entered '0'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:16:59', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03329568-c066-4d11-a08d-a7639ed21f07'	System	27 Aug 2020 23:17:04
User entered '27 Aug 2020 19:16'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Aug 2020 23:17:04
User entered 'Day 8'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '68646b04-2dba-4d72-ba25-b5e835750466'	System	29 Aug 2020 00:52:17
User entered 'Yes (Y)'	System	29 Aug 2020 00:52:17

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '68646b04-2dba-4d72-ba25-b5e835750466'	System	29 Aug 2020 00:52:17
User entered '99.4'	System	29 Aug 2020 00:52:17

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '68646b04-2dba-4d72-ba25-b5e835750466'	System	29 Aug 2020 00:52:17
User entered 'No (N)'	System	29 Aug 2020 00:52:17

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '68646b04-2dba-4d72-ba25-b5e835750466'	System	29 Aug 2020 00:52:17
User entered '28 Aug 2020 20:52'	System	29 Aug 2020 00:52:17

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:31:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a34da5f5-3ed8-44b4-9563-54e857253f59'	System	21 Aug 2020 19:31:46
User entered 'None (1)'	System	21 Aug 2020 19:31:46

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:31:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a34da5f5-3ed8-44b4-9563-54e857253f59'	System	21 Aug 2020 19:31:46
User entered 'No (N)'	System	21 Aug 2020 19:31:46

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:31:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a34da5f5-3ed8-44b4-9563-54e857253f59'	System	21 Aug 2020 19:31:46
User entered 'No (N)'	System	21 Aug 2020 19:31:46

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:31:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a34da5f5-3ed8-44b4-9563-54e857253f59'	System	21 Aug 2020 19:31:46
User entered 'None (1)'	System	21 Aug 2020 19:31:46

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:31:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a34da5f5-3ed8-44b4-9563-54e857253f59'	System	21 Aug 2020 19:31:46
User entered '21 Aug 2020 15:31'	System	21 Aug 2020 19:31:46

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Aug 2020 15:16'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Aug 2020 17:46'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:44:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64079fa2-739d-43fe-80bf-94f19f720a1b'	System	21 Aug 2020 22:46:02
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	21 Aug 2020 22:46:02

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:44:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64079fa2-739d-43fe-80bf-94f19f720a1b'	System	21 Aug 2020 22:46:02
User entered 'No (N)'	System	21 Aug 2020 22:46:02

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:44:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64079fa2-739d-43fe-80bf-94f19f720a1b'	System	21 Aug 2020 22:46:02
User entered 'Yes (Y)'	System	21 Aug 2020 22:46:02

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:45:37', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64079fa2-739d-43fe-80bf-94f19f720a1b'	System	21 Aug 2020 22:46:02
User entered '40'	System	21 Aug 2020 22:46:02

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:45:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64079fa2-739d-43fe-80bf-94f19f720a1b'	System	21 Aug 2020 22:46:02
User entered 'None (1)'	System	21 Aug 2020 22:46:02

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:46:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64079fa2-739d-43fe-80bf-94f19f720a1b'	System	21 Aug 2020 22:46:02
User entered '21 Aug 2020 18:46'	System	21 Aug 2020 22:46:02

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Aug 2020 18:41'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 2'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:16:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'aa217513-9735-402e-ade4-ab2f72d80dc0'	System	22 Aug 2020 17:17:33
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Aug 2020 17:17:33

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:17:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'aa217513-9735-402e-ade4-ab2f72d80dc0'	System	22 Aug 2020 17:17:33
User entered 'No (N)'	System	22 Aug 2020 17:17:33

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:17:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'aa217513-9735-402e-ade4-ab2f72d80dc0'	System	22 Aug 2020 17:17:33
User entered 'No (N)'	System	22 Aug 2020 17:17:33

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:17:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'aa217513-9735-402e-ade4-ab2f72d80dc0'	System	22 Aug 2020 17:17:33
User entered 'None (1)'	System	22 Aug 2020 17:17:33

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:17:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'aa217513-9735-402e-ade4-ab2f72d80dc0'	System	22 Aug 2020 17:17:33
User entered '22 Aug 2020 13:17'	System	22 Aug 2020 17:17:33

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 3'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a17a67c4-d178-498d-9899-bd5df2dc7a1f'	System	23 Aug 2020 19:42:48
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 19:42:48

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a17a67c4-d178-498d-9899-bd5df2dc7a1f'	System	23 Aug 2020 19:42:48
User entered 'No (N)'	System	23 Aug 2020 19:42:48

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:39', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a17a67c4-d178-498d-9899-bd5df2dc7a1f'	System	23 Aug 2020 19:42:48
User entered 'No (N)'	System	23 Aug 2020 19:42:48

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a17a67c4-d178-498d-9899-bd5df2dc7a1f'	System	23 Aug 2020 19:42:48
User entered 'None (1)'	System	23 Aug 2020 19:42:48

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a17a67c4-d178-498d-9899-bd5df2dc7a1f'	System	23 Aug 2020 19:42:48
User entered '23 Aug 2020 15:42'	System	23 Aug 2020 19:42:48

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 4'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ca98909e-d80d-47d3-a94a-a6ce416acb10'	System	24 Aug 2020 21:54:38
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 21:54:38

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ca98909e-d80d-47d3-a94a-a6ce416acb10'	System	24 Aug 2020 21:54:38
User entered 'No (N)'	System	24 Aug 2020 21:54:38

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ca98909e-d80d-47d3-a94a-a6ce416acb10'	System	24 Aug 2020 21:54:38
User entered 'No (N)'	System	24 Aug 2020 21:54:38

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ca98909e-d80d-47d3-a94a-a6ce416acb10'	System	24 Aug 2020 21:54:38
User entered 'None (1)'	System	24 Aug 2020 21:54:38

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ca98909e-d80d-47d3-a94a-a6ce416acb10'	System	24 Aug 2020 21:54:38
User entered '24 Aug 2020 17:54'	System	24 Aug 2020 21:54:38

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 5'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:38', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e36a1bb8-c4a4-42c6-804f-8a5be371c1f0'	System	25 Aug 2020 19:54:53
User entered 'None (1)'	System	25 Aug 2020 19:54:53

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e36a1bb8-c4a4-42c6-804f-8a5be371c1f0'	System	25 Aug 2020 19:54:53
User entered 'No (N)'	System	25 Aug 2020 19:54:53

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e36a1bb8-c4a4-42c6-804f-8a5be371c1f0'	System	25 Aug 2020 19:54:53
User entered 'No (N)'	System	25 Aug 2020 19:54:53

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e36a1bb8-c4a4-42c6-804f-8a5be371c1f0'	System	25 Aug 2020 19:54:53
User entered 'None (1)'	System	25 Aug 2020 19:54:53

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:54:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e36a1bb8-c4a4-42c6-804f-8a5be371c1f0'	System	25 Aug 2020 19:54:53
User entered '25 Aug 2020 15:54'	System	25 Aug 2020 19:54:53

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 6'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:36:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4ac1f149-4020-418b-a23a-966da2be6d6d'	System	26 Aug 2020 19:37:11
User entered 'None (1)'	System	26 Aug 2020 19:37:11

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:36:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4ac1f149-4020-418b-a23a-966da2be6d6d'	System	26 Aug 2020 19:37:11
User entered 'No (N)'	System	26 Aug 2020 19:37:11

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4ac1f149-4020-418b-a23a-966da2be6d6d'	System	26 Aug 2020 19:37:11
User entered 'No (N)'	System	26 Aug 2020 19:37:11

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4ac1f149-4020-418b-a23a-966da2be6d6d'	System	26 Aug 2020 19:37:11
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 19:37:11

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:09', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4ac1f149-4020-418b-a23a-966da2be6d6d'	System	26 Aug 2020 19:37:11
User entered '26 Aug 2020 15:37'	System	26 Aug 2020 19:37:11

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 7'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:17:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '17fbae28-d0ff-47af-95a5-54ef869c7cfe'	System	27 Aug 2020 23:18:47
User entered 'None (1)'	System	27 Aug 2020 23:18:47

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:18:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '17fbae28-d0ff-47af-95a5-54ef869c7cfe'	System	27 Aug 2020 23:18:47
User entered 'No (N)'	System	27 Aug 2020 23:18:47

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:18:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '17fbae28-d0ff-47af-95a5-54ef869c7cfe'	System	27 Aug 2020 23:18:47
User entered 'No (N)'	System	27 Aug 2020 23:18:47

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:18:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '17fbae28-d0ff-47af-95a5-54ef869c7cfe'	System	27 Aug 2020 23:18:47
User entered 'None (1)'	System	27 Aug 2020 23:18:47

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:18:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '17fbae28-d0ff-47af-95a5-54ef869c7cfe'	System	27 Aug 2020 23:18:47
User entered '27 Aug 2020 19:18'	System	27 Aug 2020 23:18:47

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:31:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3db91ddd-8016-4e20-951e-02a48841affc'	System	21 Aug 2020 19:32:36
User entered 'None (0)'	System	21 Aug 2020 19:32:36

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:32:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3db91ddd-8016-4e20-951e-02a48841affc'	System	21 Aug 2020 19:32:36
User entered 'None (0)'	System	21 Aug 2020 19:32:36

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:32:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3db91ddd-8016-4e20-951e-02a48841affc'	System	21 Aug 2020 19:32:36
User entered 'None (0)'	System	21 Aug 2020 19:32:36

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:32:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3db91ddd-8016-4e20-951e-02a48841affc'	System	21 Aug 2020 19:32:36
User entered 'None (0)'	System	21 Aug 2020 19:32:36

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:32:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3db91ddd-8016-4e20-951e-02a48841affc'	System	21 Aug 2020 19:32:36
User entered 'None (0)'	System	21 Aug 2020 19:32:36

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:32:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3db91ddd-8016-4e20-951e-02a48841affc'	System	21 Aug 2020 19:32:36
User entered 'None (0)'	System	21 Aug 2020 19:32:36

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:32:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3db91ddd-8016-4e20-951e-02a48841affc'	System	21 Aug 2020 19:32:36
User entered 'No (N)'	System	21 Aug 2020 19:32:36

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T15:32:34', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3db91ddd-8016-4e20-951e-02a48841affc'	System	21 Aug 2020 19:32:36
User entered '21 Aug 2020 15:32'	System	21 Aug 2020 19:32:36

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Aug 2020 15:16'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Aug 2020 17:46'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:46:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6affe838-b0d4-4157-a61c-4f7713e0501f'	System	21 Aug 2020 22:46:45
User entered 'None (0)'	System	21 Aug 2020 22:46:45

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:46:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6affe838-b0d4-4157-a61c-4f7713e0501f'	System	21 Aug 2020 22:46:45
User entered 'No interference with activity (1)'	System	21 Aug 2020 22:46:45

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:46:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6affe838-b0d4-4157-a61c-4f7713e0501f'	System	21 Aug 2020 22:46:45
User entered 'None (0)'	System	21 Aug 2020 22:46:45

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:46:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6affe838-b0d4-4157-a61c-4f7713e0501f'	System	21 Aug 2020 22:46:45
User entered 'None (0)'	System	21 Aug 2020 22:46:45

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:46:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6affe838-b0d4-4157-a61c-4f7713e0501f'	System	21 Aug 2020 22:46:45
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Aug 2020 22:46:45

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:46:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6affe838-b0d4-4157-a61c-4f7713e0501f'	System	21 Aug 2020 22:46:45
User entered 'No interference with activity (1)'	System	21 Aug 2020 22:46:45

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:46:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6affe838-b0d4-4157-a61c-4f7713e0501f'	System	21 Aug 2020 22:46:45
User entered 'No (N)'	System	21 Aug 2020 22:46:45

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-21T18:46:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6affe838-b0d4-4157-a61c-4f7713e0501f'	System	21 Aug 2020 22:46:45
User entered '21 Aug 2020 18:46'	System	21 Aug 2020 22:46:45

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Aug 2020 18:41'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 2'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:17:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64939a85-91dd-4eeb-8c72-b6c7cc8cd415'	System	22 Aug 2020 17:18:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 17:18:16

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:17:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64939a85-91dd-4eeb-8c72-b6c7cc8cd415'	System	22 Aug 2020 17:18:16
User entered 'Some interference with activity (2)'	System	22 Aug 2020 17:18:16

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:17:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64939a85-91dd-4eeb-8c72-b6c7cc8cd415'	System	22 Aug 2020 17:18:16
User entered 'Some interference with activity (2)'	System	22 Aug 2020 17:18:16

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:17:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64939a85-91dd-4eeb-8c72-b6c7cc8cd415'	System	22 Aug 2020 17:18:16
User entered 'Some interference with activity (2)'	System	22 Aug 2020 17:18:16

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:18:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64939a85-91dd-4eeb-8c72-b6c7cc8cd415'	System	22 Aug 2020 17:18:16
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Aug 2020 17:18:16

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:18:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64939a85-91dd-4eeb-8c72-b6c7cc8cd415'	System	22 Aug 2020 17:18:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 17:18:16

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:18:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64939a85-91dd-4eeb-8c72-b6c7cc8cd415'	System	22 Aug 2020 17:18:16
User entered 'No (N)'	System	22 Aug 2020 17:18:16

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-22T13:18:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64939a85-91dd-4eeb-8c72-b6c7cc8cd415'	System	22 Aug 2020 17:18:16
User entered '22 Aug 2020 13:18'	System	22 Aug 2020 17:18:16

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 3'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd4d62294-6e96-4dbc-991f-553525f77b37'	System	23 Aug 2020 19:43:17
User entered 'None (0)'	System	23 Aug 2020 19:43:17

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd4d62294-6e96-4dbc-991f-553525f77b37'	System	23 Aug 2020 19:43:17
User entered 'No interference with activity (1)'	System	23 Aug 2020 19:43:17

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:42:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd4d62294-6e96-4dbc-991f-553525f77b37'	System	23 Aug 2020 19:43:17
User entered 'None (0)'	System	23 Aug 2020 19:43:17

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:43:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd4d62294-6e96-4dbc-991f-553525f77b37'	System	23 Aug 2020 19:43:17
User entered 'No interference with activity (1)'	System	23 Aug 2020 19:43:17

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:43:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd4d62294-6e96-4dbc-991f-553525f77b37'	System	23 Aug 2020 19:43:17
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Aug 2020 19:43:17

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:43:09', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd4d62294-6e96-4dbc-991f-553525f77b37'	System	23 Aug 2020 19:43:17
User entered 'None (0)'	System	23 Aug 2020 19:43:17

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:43:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd4d62294-6e96-4dbc-991f-553525f77b37'	System	23 Aug 2020 19:43:17
User entered 'No (N)'	System	23 Aug 2020 19:43:17

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-23T15:43:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd4d62294-6e96-4dbc-991f-553525f77b37'	System	23 Aug 2020 19:43:17
User entered '23 Aug 2020 15:43'	System	23 Aug 2020 19:43:17

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 4'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:39', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9c855bf7-5836-411e-bbee-15bed75784e8'	System	24 Aug 2020 21:55:04
User entered 'None (0)'	System	24 Aug 2020 21:55:04

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9c855bf7-5836-411e-bbee-15bed75784e8'	System	24 Aug 2020 21:55:04
User entered 'No interference with activity (1)'	System	24 Aug 2020 21:55:04

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9c855bf7-5836-411e-bbee-15bed75784e8'	System	24 Aug 2020 21:55:04
User entered 'None (0)'	System	24 Aug 2020 21:55:04

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9c855bf7-5836-411e-bbee-15bed75784e8'	System	24 Aug 2020 21:55:04
User entered 'No interference with activity (1)'	System	24 Aug 2020 21:55:04

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9c855bf7-5836-411e-bbee-15bed75784e8'	System	24 Aug 2020 21:55:04
User entered 'None (0)'	System	24 Aug 2020 21:55:04

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:55', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9c855bf7-5836-411e-bbee-15bed75784e8'	System	24 Aug 2020 21:55:04
User entered 'None (0)'	System	24 Aug 2020 21:55:04

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:54:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9c855bf7-5836-411e-bbee-15bed75784e8'	System	24 Aug 2020 21:55:04
User entered 'No (N)'	System	24 Aug 2020 21:55:04

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-24T17:55:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9c855bf7-5836-411e-bbee-15bed75784e8'	System	24 Aug 2020 21:55:04
User entered '24 Aug 2020 17:55'	System	24 Aug 2020 21:55:04

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 5'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:55:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8433b289-4943-4b55-9347-f1dbaf757995'	System	25 Aug 2020 19:55:28
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	25 Aug 2020 19:55:28

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:55:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8433b289-4943-4b55-9347-f1dbaf757995'	System	25 Aug 2020 19:55:28
User entered 'No interference with activity (1)'	System	25 Aug 2020 19:55:28

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:55:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8433b289-4943-4b55-9347-f1dbaf757995'	System	25 Aug 2020 19:55:28
User entered 'No interference with activity (1)'	System	25 Aug 2020 19:55:28

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:55:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8433b289-4943-4b55-9347-f1dbaf757995'	System	25 Aug 2020 19:55:28
User entered 'No interference with activity (1)'	System	25 Aug 2020 19:55:28

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:55:18', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8433b289-4943-4b55-9347-f1dbaf757995'	System	25 Aug 2020 19:55:28
User entered 'None (0)'	System	25 Aug 2020 19:55:28

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:55:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8433b289-4943-4b55-9347-f1dbaf757995'	System	25 Aug 2020 19:55:28
User entered 'None (0)'	System	25 Aug 2020 19:55:28

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:55:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8433b289-4943-4b55-9347-f1dbaf757995'	System	25 Aug 2020 19:55:28
User entered 'No (N)'	System	25 Aug 2020 19:55:28

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-25T15:55:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8433b289-4943-4b55-9347-f1dbaf757995'	System	25 Aug 2020 19:55:28
User entered '25 Aug 2020 15:55'	System	25 Aug 2020 19:55:28

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 6'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '144379e9-e48d-44a8-826b-1cf85699b4b1'	System	26 Aug 2020 19:37:35
User entered 'None (0)'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '144379e9-e48d-44a8-826b-1cf85699b4b1'	System	26 Aug 2020 19:37:35
User entered 'No interference with activity (1)'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:18', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '144379e9-e48d-44a8-826b-1cf85699b4b1'	System	26 Aug 2020 19:37:35
User entered 'None (0)'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '144379e9-e48d-44a8-826b-1cf85699b4b1'	System	26 Aug 2020 19:37:35
User entered 'No interference with activity (1)'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '144379e9-e48d-44a8-826b-1cf85699b4b1'	System	26 Aug 2020 19:37:35
User entered 'None (0)'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '144379e9-e48d-44a8-826b-1cf85699b4b1'	System	26 Aug 2020 19:37:35
User entered 'None (0)'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '144379e9-e48d-44a8-826b-1cf85699b4b1'	System	26 Aug 2020 19:37:35
User entered 'No (N)'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-26T15:37:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '144379e9-e48d-44a8-826b-1cf85699b4b1'	System	26 Aug 2020 19:37:35
User entered '26 Aug 2020 15:37'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 7'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:18:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4c59f978-8396-48d1-8104-ca4dfc443f12'	System	27 Aug 2020 23:21:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:18:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4c59f978-8396-48d1-8104-ca4dfc443f12'	System	27 Aug 2020 23:21:09
User entered 'No interference with activity (1)'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:20:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4c59f978-8396-48d1-8104-ca4dfc443f12'	System	27 Aug 2020 23:21:09
User entered 'None (0)'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:20:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4c59f978-8396-48d1-8104-ca4dfc443f12'	System	27 Aug 2020 23:21:09
User entered 'No interference with activity (1)'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:21:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4c59f978-8396-48d1-8104-ca4dfc443f12'	System	27 Aug 2020 23:21:09
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:21:02', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4c59f978-8396-48d1-8104-ca4dfc443f12'	System	27 Aug 2020 23:21:09
User entered 'None (0)'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:21:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4c59f978-8396-48d1-8104-ca4dfc443f12'	System	27 Aug 2020 23:21:09
User entered 'No (N)'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-27T19:21:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4c59f978-8396-48d1-8104-ca4dfc443f12'	System	27 Aug 2020 23:21:09
User entered '27 Aug 2020 19:21'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Aug 2020 23:21:09
User entered 'Day 8'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4ee4462d-8c96-4839-8ce2-c4cfd8799d18'	System	29 Aug 2020 00:52:32
User entered 'None (0)'	System	29 Aug 2020 00:52:32

US3672255

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4ee4462d-8c96-4839-8ce2-c4cfd8799d18'	System	29 Aug 2020 00:52:32
User entered '28 Aug 2020 20:52'	System	29 Aug 2020 00:52:32

US3672255

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	26 Aug 2020 19:37:35
User entered 'Day 8'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c9ec3eef-f749-45d6-96a4-f3bb45a225c4'	System	29 Aug 2020 00:52:39
User entered 'No interference with activity (1)'	System	29 Aug 2020 00:52:39

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c9ec3eef-f749-45d6-96a4-f3bb45a225c4'	System	29 Aug 2020 00:52:39
User entered '28 Aug 2020 20:52'	System	29 Aug 2020 00:52:39

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Aug 2020 23:21:09
User entered 'Day 9'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-29T18:49:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '92c54c0b-f7ac-4aa5-a4cf-69bc5fad2a58'	System	29 Aug 2020 22:49:10
User entered 'No interference with activity (1)'	System	29 Aug 2020 22:49:10

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-29T18:49:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '92c54c0b-f7ac-4aa5-a4cf-69bc5fad2a58'	System	29 Aug 2020 22:49:10
User entered '29 Aug 2020 18:49'	System	29 Aug 2020 22:49:10

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Aug 2020 00:52:39
User entered 'Day 10'	System	29 Aug 2020 00:52:39

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-30T13:21:32', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd2c5d65b-0c4c-40a0-a32d-6777300459a4'	System	30 Aug 2020 17:21:38
User entered 'No interference with activity (1)'	System	30 Aug 2020 17:21:38

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-30T13:21:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd2c5d65b-0c4c-40a0-a32d-6777300459a4'	System	30 Aug 2020 17:21:38
User entered '30 Aug 2020 13:21'	System	30 Aug 2020 17:21:38

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 00:52:39

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 00:52:39

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Aug 2020 22:49:10
User entered 'Day 11'	System	29 Aug 2020 22:49:10

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-31T16:34:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3975b4be-17fc-4663-9894-2492410507a4'	System	31 Aug 2020 20:34:20
User entered 'No interference with activity (1)'	System	31 Aug 2020 20:34:20

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-31T16:34:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3975b4be-17fc-4663-9894-2492410507a4'	System	31 Aug 2020 20:34:20
User entered '31 Aug 2020 16:34'	System	31 Aug 2020 20:34:20

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 22:49:10

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 22:49:10

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	30 Aug 2020 17:21:38
User entered 'Day 12'	System	30 Aug 2020 17:21:38

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-01T23:59:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '547f132b-ebc8-424c-8acb-844e5ba9246f'	System	02 Sep 2020 03:59:47
User entered 'No interference with activity (1)'	System	02 Sep 2020 03:59:47

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-01T23:59:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '547f132b-ebc8-424c-8acb-844e5ba9246f'	System	02 Sep 2020 03:59:47
User entered '01 Sep 2020 23:59'	System	02 Sep 2020 03:59:47

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:21:38

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:21:38

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	31 Aug 2020 20:34:20
User entered 'Day 13'	System	31 Aug 2020 20:34:20

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-02T17:28:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '42722198-1e8f-49b1-b139-5144d67eac73'	System	02 Sep 2020 21:29:00
User entered 'No interference with activity (1)'	System	02 Sep 2020 21:29:00

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-02T17:28:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '42722198-1e8f-49b1-b139-5144d67eac73'	System	02 Sep 2020 21:29:00
User entered '02 Sep 2020 17:28'	System	02 Sep 2020 21:29:00

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:34:20

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:34:20

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Sep 2020 03:59:47
User entered 'Day 14'	System	02 Sep 2020 03:59:47

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-03T20:54:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '948952e2-bc95-4dd0-b885-ca45197d0893'	System	04 Sep 2020 00:55:01
User entered 'No interference with activity (1)'	System	04 Sep 2020 00:55:01

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-03T20:54:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '948952e2-bc95-4dd0-b885-ca45197d0893'	System	04 Sep 2020 00:55:01
User entered '03 Sep 2020 20:54'	System	04 Sep 2020 00:55:01

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 03:59:47

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 03:59:47

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Sep 2020 21:29:00
User entered 'Day 15'	System	02 Sep 2020 21:29:00

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-04T16:16:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '59d67d8c-8c33-438e-bdf8-119d41d9ef61'	System	04 Sep 2020 20:16:50
User entered 'No interference with activity (1)'	System	04 Sep 2020 20:16:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-04T16:16:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '59d67d8c-8c33-438e-bdf8-119d41d9ef61'	System	04 Sep 2020 20:16:50
User entered '04 Sep 2020 16:16'	System	04 Sep 2020 20:16:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:29:00

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:29:00

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Sep 2020 00:55:01
User entered 'Day 16'	System	04 Sep 2020 00:55:01

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-05T18:54:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '452d5dd1-001b-4171-811f-88172d59b108'	System	05 Sep 2020 22:54:11
User entered 'No interference with activity (1)'	System	05 Sep 2020 22:54:11

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-05T18:54:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '452d5dd1-001b-4171-811f-88172d59b108'	System	05 Sep 2020 22:54:11
User entered '05 Sep 2020 18:54'	System	05 Sep 2020 22:54:11

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 00:55:01

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 00:55:01

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Sep 2020 20:16:50
User entered 'Day 17'	System	04 Sep 2020 20:16:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-06T15:01:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1e0007ab-861a-422c-bd65-aba69277b8d6'	System	06 Sep 2020 19:02:05
User entered 'No interference with activity (1)'	System	06 Sep 2020 19:02:05

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-06T15:02:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1e0007ab-861a-422c-bd65-aba69277b8d6'	System	06 Sep 2020 19:02:05
User entered '06 Sep 2020 15:02'	System	06 Sep 2020 19:02:05

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:16:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:16:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	05 Sep 2020 22:54:11
User entered 'Day 18'	System	05 Sep 2020 22:54:11

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-07T16:39:18', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0e74f6e8-4486-401d-ae3a-2bf044c21fee'	System	07 Sep 2020 20:39:24
User entered 'No interference with activity (1)'	System	07 Sep 2020 20:39:24

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-07T16:39:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0e74f6e8-4486-401d-ae3a-2bf044c21fee'	System	07 Sep 2020 20:39:24
User entered '07 Sep 2020 16:39'	System	07 Sep 2020 20:39:24

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 22:54:11

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 22:54:11

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	06 Sep 2020 19:02:05
User entered 'Day 19'	System	06 Sep 2020 19:02:05

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-08T12:26:38', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1c07d1f8-46ff-4586-9255-c1033e241dda'	System	08 Sep 2020 16:26:45
User entered 'Some interference with activity (2)'	System	08 Sep 2020 16:26:45

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-08T12:26:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1c07d1f8-46ff-4586-9255-c1033e241dda'	System	08 Sep 2020 16:26:45
User entered '08 Sep 2020 12:26'	System	08 Sep 2020 16:26:45

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 19:02:05

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 19:02:05

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	07 Sep 2020 20:39:24
User entered 'Day 20'	System	07 Sep 2020 20:39:24

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-09T14:19:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4af3ab59-cf17-4a8b-b692-7d0eef98c986'	System	09 Sep 2020 18:19:29
User entered 'No interference with activity (1)'	System	09 Sep 2020 18:19:29

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-09T14:19:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4af3ab59-cf17-4a8b-b692-7d0eef98c986'	System	09 Sep 2020 18:19:29
User entered '09 Sep 2020 14:19'	System	09 Sep 2020 18:19:29

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 20:39:24

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 20:39:24

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	08 Sep 2020 16:26:45
User entered 'Day 21'	System	08 Sep 2020 16:26:45

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-10T16:37:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5687df48-1a44-422b-991d-d8860bfeac6d'	System	10 Sep 2020 20:37:26
User entered 'No interference with activity (1)'	System	10 Sep 2020 20:37:26

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-10T16:37:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5687df48-1a44-422b-991d-d8860bfeac6d' User entered '10 Sep 2020 16:37'	System	10 Sep 2020 20:37:26
	System	10 Sep 2020 20:37:26

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:26:45

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:26:45

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Sep 2020 18:19:29
User entered 'Day 22'	System	09 Sep 2020 18:19:29

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-11T13:16:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'fba78adb-aa5f-472e-86e1-b43f7a15acfd'	System	11 Sep 2020 17:16:08
User entered 'Some interference with activity (2)'	System	11 Sep 2020 17:16:08

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-11T13:16:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'fba78adb-aa5f-472e-86e1-b43f7a15acfd'	System	11 Sep 2020 17:16:08
User entered '11 Sep 2020 13:16'	System	11 Sep 2020 17:16:08

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:19:29

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:19:29

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	10 Sep 2020 20:37:26
User entered 'Day 23'	System	10 Sep 2020 20:37:26

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-12T15:46:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ce69cb25-21e7-4ba0-8cf4-916014bb7847'	System	12 Sep 2020 19:46:51
User entered 'Some interference with activity (2)'	System	12 Sep 2020 19:46:51

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-12T15:46:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ce69cb25-21e7-4ba0-8cf4-916014bb7847'	System	12 Sep 2020 19:46:51
User entered '12 Sep 2020 15:46'	System	12 Sep 2020 19:46:51

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:37:26

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:37:26

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	11 Sep 2020 17:16:08
User entered 'Day 24'	System	11 Sep 2020 17:16:08

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-13T15:16:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '430794eb-a938-44ee-86aa-97d8cd0b7629'	System	13 Sep 2020 19:16:53
User entered 'No interference with activity (1)'	System	13 Sep 2020 19:16:53

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-13T15:16:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '430794eb-a938-44ee-86aa-97d8cd0b7629'	System	13 Sep 2020 19:16:53
User entered '13 Sep 2020 15:16'	System	13 Sep 2020 19:16:53

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:16:08

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:16:08

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Sep 2020 19:46:51
User entered 'Day 25'	System	12 Sep 2020 19:46:51

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-14T17:32:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47d12e0a-8b9c-4ecb-b5b6-e9bae77d4b5f'	System	14 Sep 2020 21:32:46
User entered 'No interference with activity (1)'	System	14 Sep 2020 21:32:46

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-14T17:32:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47d12e0a-8b9c-4ecb-b5b6-e9bae77d4b5f'	System	14 Sep 2020 21:32:46
User entered '14 Sep 2020 17:32'	System	14 Sep 2020 21:32:46

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 19:46:51

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 19:46:51

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	13 Sep 2020 19:16:53
User entered 'Day 26'	System	13 Sep 2020 19:16:53

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-15T22:22:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '414651ab-d67e-4f5c-b6b8-8aa5ffdeb73b'	System	16 Sep 2020 02:22:37
User entered 'No interference with activity (1)'	System	16 Sep 2020 02:22:37

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-15T22:22:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '414651ab-d67e-4f5c-b6b8-8aa5ffdeb73b'	System	16 Sep 2020 02:22:37
User entered '15 Sep 2020 22:22'	System	16 Sep 2020 02:22:37

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 19:16:53

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 19:16:53

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	14 Sep 2020 21:32:46
User entered 'Day 27'	System	14 Sep 2020 21:32:46

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-16T15:15:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7e776750-63c7-4e66-a9b9-5c8b4c2e5f73'	System	16 Sep 2020 19:15:41
User entered 'No interference with activity (1)'	System	16 Sep 2020 19:15:41

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-16T15:15:38', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7e776750-63c7-4e66-a9b9-5c8b4c2e5f73'	System	16 Sep 2020 19:15:41
User entered '16 Sep 2020 15:15'	System	16 Sep 2020 19:15:41

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:32:46

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:32:46

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	16 Sep 2020 02:22:37
User entered 'Day 28'	System	16 Sep 2020 02:22:37

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-17T23:59:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd13c0ba5-b47a-4a9d-8627-5b6ec22acc2d'	System	18 Sep 2020 03:59:50
User entered 'No interference with activity (1)'	System	18 Sep 2020 03:59:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-17T23:59:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd13c0ba5-b47a-4a9d-8627-5b6ec22acc2d'	System	18 Sep 2020 03:59:50
User entered '17 Sep 2020 23:59'	System	18 Sep 2020 03:59:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 02:22:37

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 02:22:37

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	16 Sep 2020 19:15:41
User entered 'Day 29'	System	16 Sep 2020 19:15:41

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 10 Jun 2021 09:24:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-18T20:21:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6d3724bf-1804-4143-8676-0a1341508f67'	System	19 Sep 2020 00:21:30
User entered 'No interference with activity (1)'	System	19 Sep 2020 00:21:30

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-18T20:21:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '6d3724bf-1804-4143-8676-0a1341508f67'	System	19 Sep 2020 00:21:30
User entered '18 Sep 2020 20:21'	System	19 Sep 2020 00:21:30

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:15:41

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:15:41

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	18 Sep 2020 03:59:50
User entered 'Day 30'	System	18 Sep 2020 03:59:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-19T21:04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '767ed3ab-700d-4cf4-b87d-4c74e89f36d0'	System	20 Sep 2020 01:04:07
User entered 'Some interference with activity (2)'	System	20 Sep 2020 01:04:07

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-19T21:04:02', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '767ed3ab-700d-4cf4-b87d-4c74e89f36d0'	System	20 Sep 2020 01:04:07
User entered '19 Sep 2020 21:04'	System	20 Sep 2020 01:04:07

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 03:59:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 03:59:50

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	19 Sep 2020 00:21:30
User entered 'Day 31'	System	19 Sep 2020 00:21:30

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-20T14:36:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'fec53c2b-20bf-4f9a-9ee5-68935a5d2012'	System	20 Sep 2020 18:36:27
User entered 'No interference with activity (1)'	System	20 Sep 2020 18:36:27

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-20T14:36:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'fec53c2b-20bf-4f9a-9ee5-68935a5d2012'	System	20 Sep 2020 18:36:27
User entered '20 Sep 2020 14:36'	System	20 Sep 2020 18:36:27

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:21:30

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:21:30

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	20 Sep 2020 01:04:07
User entered 'Day 32'	System	20 Sep 2020 01:04:07

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-21T15:35:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '886413d7-595d-46ee-b062-a19108ce86ca'	System	21 Sep 2020 19:35:51
User entered 'Some interference with activity (2)'	System	21 Sep 2020 19:35:51

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-21T15:35:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '886413d7-595d-46ee-b062-a19108ce86ca'	System	21 Sep 2020 19:35:51
User entered '21 Sep 2020 15:35'	System	21 Sep 2020 19:35:51

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 01:04:07

US3672255

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 01:04:07

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	26 Aug 2020 19:37:35
User entered 'Day 8'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b1267756-1ebe-4046-a93c-2380941b1aff'	System	29 Aug 2020 00:52:47
User entered 'No interference with activity (1)'	System	29 Aug 2020 00:52:47

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b1267756-1ebe-4046-a93c-2380941b1aff'	System	29 Aug 2020 00:52:47
User entered '28 Aug 2020 20:52'	System	29 Aug 2020 00:52:47

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:37:35

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Aug 2020 23:21:09
User entered 'Day 9'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-29T18:49:18', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '36d1f505-e96b-440d-863c-a12a1c78ce90'	System	29 Aug 2020 22:49:27
User entered 'No interference with activity (1)'	System	29 Aug 2020 22:49:27

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-29T18:49:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '36d1f505-e96b-440d-863c-a12a1c78ce90'	System	29 Aug 2020 22:49:27
User entered '29 Aug 2020 18:49'	System	29 Aug 2020 22:49:27

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Aug 2020 00:52:47
User entered 'Day 10'	System	29 Aug 2020 00:52:47

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-30T13:21:39', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a6c6bae3-9818-4e73-8598-4202a246a91e'	System	30 Aug 2020 17:21:45
User entered 'No interference with activity (1)'	System	30 Aug 2020 17:21:45

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-30T13:21:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a6c6bae3-9818-4e73-8598-4202a246a91e'	System	30 Aug 2020 17:21:45
User entered '30 Aug 2020 13:21'	System	30 Aug 2020 17:21:45

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 00:52:47

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 00:52:47

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Aug 2020 22:49:27
User entered 'Day 11'	System	29 Aug 2020 22:49:27

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-31T16:34:18', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03b671fb-108f-4735-be7b-17199bd537d2'	System	31 Aug 2020 20:34:26
User entered 'No interference with activity (1)'	System	31 Aug 2020 20:34:26

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-31T16:34:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03b671fb-108f-4735-be7b-17199bd537d2'	System	31 Aug 2020 20:34:26
User entered '31 Aug 2020 16:34'	System	31 Aug 2020 20:34:26

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 22:49:27

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 22:49:27

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	30 Aug 2020 17:21:45
User entered 'Day 12'	System	30 Aug 2020 17:21:45

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-01T23:59:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c8dbdb28-1ae8-4887-83db-1e66309f6210'	System	02 Sep 2020 03:59:49
User entered 'No interference with activity (1)'	System	02 Sep 2020 03:59:49

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-01T23:59:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c8dbdb28-1ae8-4887-83db-1e66309f6210'	System	02 Sep 2020 03:59:49
User entered '01 Sep 2020 23:59'	System	02 Sep 2020 03:59:49

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:21:45

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:21:45

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	31 Aug 2020 20:34:26
User entered 'Day 13'	System	31 Aug 2020 20:34:26

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-02T17:29:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2e14270a-7068-4f17-b4aa-16ecc784d913'	System	02 Sep 2020 21:29:09
User entered 'No interference with activity (1)'	System	02 Sep 2020 21:29:09

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-02T17:29:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2e14270a-7068-4f17-b4aa-16ecc784d913'	System	02 Sep 2020 21:29:09
User entered '02 Sep 2020 17:29'	System	02 Sep 2020 21:29:09

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:34:26

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:34:26

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Sep 2020 03:59:49
User entered 'Day 14'	System	02 Sep 2020 03:59:49

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-03T20:55:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2f805d4f-d473-4a38-ac99-195a2f27a638'	System	04 Sep 2020 00:55:10
User entered 'No interference with activity (1)'	System	04 Sep 2020 00:55:10

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-03T20:55:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2f805d4f-d473-4a38-ac99-195a2f27a638'	System	04 Sep 2020 00:55:10
User entered '03 Sep 2020 20:55'	System	04 Sep 2020 00:55:10

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 03:59:49

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 03:59:49

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Sep 2020 21:29:09
User entered 'Day 15'	System	02 Sep 2020 21:29:09

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-04T16:16:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ac2f9de4-57e9-4b6c-95d2-39f06db7ee2b'	System	04 Sep 2020 20:16:56
User entered 'No interference with activity (1)'	System	04 Sep 2020 20:16:56

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-04T16:16:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ac2f9de4-57e9-4b6c-95d2-39f06db7ee2b'	System	04 Sep 2020 20:16:56
User entered '04 Sep 2020 16:16'	System	04 Sep 2020 20:16:56

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:29:09

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:29:09

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Sep 2020 00:55:10
User entered 'Day 16'	System	04 Sep 2020 00:55:10

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-05T18:54:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bf34d1e3-ff68-466e-a5c0-9773929f0e8b'	System	05 Sep 2020 22:54:18
User entered 'Some interference with activity (2)'	System	05 Sep 2020 22:54:18

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-05T18:54:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bf34d1e3-ff68-466e-a5c0-9773929f0e8b' User entered '05 Sep 2020 18:54'	System	05 Sep 2020 22:54:18
	System	05 Sep 2020 22:54:18

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 00:55:10

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 00:55:10

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Sep 2020 20:16:56
User entered 'Day 17'	System	04 Sep 2020 20:16:56

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-06T15:02:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a6674bb2-a0e1-442e-b0a4-1b1b626eb737'	System	06 Sep 2020 19:02:11
User entered 'No interference with activity (1)'	System	06 Sep 2020 19:02:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-06T15:02:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a6674bb2-a0e1-442e-b0a4-1b1b626eb737'	System	06 Sep 2020 19:02:11
User entered '06 Sep 2020 15:02'	System	06 Sep 2020 19:02:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:16:56

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:16:56

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	05 Sep 2020 22:54:18
User entered 'Day 18'	System	05 Sep 2020 22:54:18

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-07T16:39:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '644ced59-c599-4254-a036-bb632203c3df'	System	07 Sep 2020 20:39:31
User entered 'Some interference with activity (2)'	System	07 Sep 2020 20:39:31

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-07T16:39:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '644ced59-c599-4254-a036-bb632203c3df' User entered '07 Sep 2020 16:39'	System	07 Sep 2020 20:39:31
	System	07 Sep 2020 20:39:31

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 22:54:18

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 22:54:18

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	06 Sep 2020 19:02:11
User entered 'Day 19'	System	06 Sep 2020 19:02:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-08T12:26:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a8acbb9e-5f97-4f73-8fae-d3c3c5043948'	System	08 Sep 2020 16:26:52
User entered 'Some interference with activity (2)'	System	08 Sep 2020 16:26:52

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-08T12:26:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a8acbb9e-5f97-4f73-8fae-d3c3c5043948'	System	08 Sep 2020 16:26:52
User entered '08 Sep 2020 12:26'	System	08 Sep 2020 16:26:52

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 19:02:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 19:02:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	07 Sep 2020 20:39:31
User entered 'Day 20'	System	07 Sep 2020 20:39:31

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-09T14:19:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9254c0e7-a78b-44d0-9341-8a06009be09e'	System	09 Sep 2020 18:19:32
User entered 'No interference with activity (1)'	System	09 Sep 2020 18:19:32

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-09T14:19:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9254c0e7-a78b-44d0-9341-8a06009be09e'	System	09 Sep 2020 18:19:32
User entered '09 Sep 2020 14:19'	System	09 Sep 2020 18:19:32

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 20:39:31

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 20:39:31

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	08 Sep 2020 16:26:52
User entered 'Day 21'	System	08 Sep 2020 16:26:52

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-10T16:37:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0e1c1a44-88a6-4125-a45b-fb3fecb1fdc4'	System	10 Sep 2020 20:37:33
User entered 'No interference with activity (1)'	System	10 Sep 2020 20:37:33

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-10T16:37:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0e1c1a44-88a6-4125-a45b-fb3fecb1fdc4'	System	10 Sep 2020 20:37:33
User entered '10 Sep 2020 16:37'	System	10 Sep 2020 20:37:33

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:26:52

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:26:52

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Sep 2020 18:19:32
User entered 'Day 22'	System	09 Sep 2020 18:19:32

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-11T13:16:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '41b19838-a2aa-4634-98d5-c15bba098bbc'	System	11 Sep 2020 17:16:14
User entered 'No interference with activity (1)'	System	11 Sep 2020 17:16:14

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-11T13:16:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '41b19838-a2aa-4634-98d5-c15bba098bbc'	System	11 Sep 2020 17:16:14
User entered '11 Sep 2020 13:16'	System	11 Sep 2020 17:16:14

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:19:32

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:19:32

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	10 Sep 2020 20:37:33
User entered 'Day 23'	System	10 Sep 2020 20:37:33

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-12T15:46:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b075aac5-ca3b-4d86-9454-cec2528b13fa'	System	12 Sep 2020 19:47:02
User entered 'No interference with activity (1)'	System	12 Sep 2020 19:47:02

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-12T15:46:59', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b075aac5-ca3b-4d86-9454-cec2528b13fa'	System	12 Sep 2020 19:47:02
User entered '12 Sep 2020 15:46'	System	12 Sep 2020 19:47:02

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:37:33

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:37:33

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	11 Sep 2020 17:16:14
User entered 'Day 24'	System	11 Sep 2020 17:16:14

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-13T15:17:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '16361d02-76cd-4452-8e2f-444f0d35a35a'	System	13 Sep 2020 19:17:11
User entered 'Some interference with activity (2)'	System	13 Sep 2020 19:17:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-13T15:17:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '16361d02-76cd-4452-8e2f-444f0d35a35a'	System	13 Sep 2020 19:17:11
User entered '13 Sep 2020 15:17'	System	13 Sep 2020 19:17:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:16:14

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:16:14

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Sep 2020 19:47:02
User entered 'Day 25'	System	12 Sep 2020 19:47:02

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-14T17:32:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '756b75aa-baaa-4d6a-8d65-c22a2e82ed5e'	System	14 Sep 2020 21:32:50
User entered 'No interference with activity (1)'	System	14 Sep 2020 21:32:50

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-14T17:32:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '756b75aa-baaa-4d6a-8d65-c22a2e82ed5e'	System	14 Sep 2020 21:32:50
User entered '14 Sep 2020 17:32'	System	14 Sep 2020 21:32:50

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 19:47:02

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 19:47:02

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	13 Sep 2020 19:17:11
User entered 'Day 26'	System	13 Sep 2020 19:17:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-15T22:22:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f2751118-a705-4b40-83d0-2ca51074d9b9'	System	16 Sep 2020 02:22:42
User entered 'No interference with activity (1)'	System	16 Sep 2020 02:22:42

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-15T22:22:38', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f2751118-a705-4b40-83d0-2ca51074d9b9'	System	16 Sep 2020 02:22:42
User entered '15 Sep 2020 22:22'	System	16 Sep 2020 02:22:42

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 19:17:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 19:17:11

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	14 Sep 2020 21:32:50
User entered 'Day 27'	System	14 Sep 2020 21:32:50

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-16T15:15:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '24c8bda1-d371-4114-8dff-5bbad91156ae'	System	16 Sep 2020 19:15:49
User entered 'None (0)'	System	16 Sep 2020 19:15:49

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-16T15:15:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '24c8bda1-d371-4114-8dff-5bbad91156ae'	System	16 Sep 2020 19:15:49
User entered '16 Sep 2020 15:15'	System	16 Sep 2020 19:15:49

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:32:50

US3672255

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:32:50

US3672255

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Aug 2020 23:21:09
User entered 'Day 8'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '651eef0e-33b2-44b4-8060-fb309bf0dae2'	System	29 Aug 2020 00:52:55
User entered 'None (0)'	System	29 Aug 2020 00:52:55

US3672255

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '651eef0e-33b2-44b4-8060-fb309bf0dae2'	System	29 Aug 2020 00:52:55
User entered '28 Aug 2020 20:52'	System	29 Aug 2020 00:52:55

US3672255

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 23:21:09

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	26 Aug 2020 19:37:11
User entered 'Day 8'	System	26 Aug 2020 19:37:11

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7f7f4503-1d6a-4b28-98d6-453762f58cb7'	System	29 Aug 2020 00:52:58
User entered 'No (N)'	System	29 Aug 2020 00:52:58

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-28T20:52:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7f7f4503-1d6a-4b28-98d6-453762f58cb7'	System	29 Aug 2020 00:52:58
User entered '28 Aug 2020 20:52'	System	29 Aug 2020 00:52:58

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:37:11

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:37:11

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Aug 2020 23:17:04
User entered 'Day 9'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-29T18:50:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b95f257b-a7b7-4d7c-86fa-e5422647fe9e'	System	29 Aug 2020 22:50:22
User entered 'No (N)'	System	29 Aug 2020 22:50:22

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-29T18:50:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b95f257b-a7b7-4d7c-86fa-e5422647fe9e'	System	29 Aug 2020 22:50:22
User entered '29 Aug 2020 18:50'	System	29 Aug 2020 22:50:22

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 23:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Aug 2020 00:52:39
User entered 'Day 10'	System	29 Aug 2020 00:52:39

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-30T13:21:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1355e4cb-9c70-4e1c-aa7a-4cf7e07b3eaf'	System	30 Aug 2020 17:21:50
User entered 'No (N)'	System	30 Aug 2020 17:21:50

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-30T13:21:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1355e4cb-9c70-4e1c-aa7a-4cf7e07b3eaf'	System	30 Aug 2020 17:21:50
User entered '30 Aug 2020 13:21'	System	30 Aug 2020 17:21:50

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 00:52:39

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 00:52:39

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Aug 2020 22:49:10
User entered 'Day 11'	System	29 Aug 2020 22:49:10

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-31T16:34:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '964080c8-0c97-4cb2-99a8-b7615d2c141a'	System	31 Aug 2020 20:34:34
User entered 'No (N)'	System	31 Aug 2020 20:34:34

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-08-31T16:34:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '964080c8-0c97-4cb2-99a8-b7615d2c141a'	System	31 Aug 2020 20:34:34
User entered '31 Aug 2020 16:34'	System	31 Aug 2020 20:34:34

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 22:49:10

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 22:49:10

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	30 Aug 2020 17:21:38
User entered 'Day 12'	System	30 Aug 2020 17:21:38

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-01T23:59:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9e7a16f6-3e54-4320-a7af-97ae36652788'	System	02 Sep 2020 03:59:57
User entered 'No (N)'	System	02 Sep 2020 03:59:57

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-01T23:59:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9e7a16f6-3e54-4320-a7af-97ae36652788'	System	02 Sep 2020 03:59:57
User entered '01 Sep 2020 23:59'	System	02 Sep 2020 03:59:57

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:21:38

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:21:38

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	31 Aug 2020 20:34:20
User entered 'Day 13'	System	31 Aug 2020 20:34:20

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-02T17:29:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f8637aa3-c026-4cb0-9567-92f046b6b74c'	System	02 Sep 2020 21:29:16
User entered 'No (N)'	System	02 Sep 2020 21:29:16

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-02T17:29:09', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f8637aa3-c026-4cb0-9567-92f046b6b74c'	System	02 Sep 2020 21:29:16
User entered '02 Sep 2020 17:29'	System	02 Sep 2020 21:29:16

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:34:20

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:34:20

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Sep 2020 03:59:47
User entered 'Day 14'	System	02 Sep 2020 03:59:47

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-03T20:55:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dd8d8727-5d4c-47c2-8b61-f1f78f6e86ec'	System	04 Sep 2020 00:55:15
User entered 'No (N)'	System	04 Sep 2020 00:55:15

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-03T20:55:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dd8d8727-5d4c-47c2-8b61-f1f78f6e86ec'	System	04 Sep 2020 00:55:15
User entered '03 Sep 2020 20:55'	System	04 Sep 2020 00:55:15

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 03:59:47

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 03:59:47

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Sep 2020 21:29:00
User entered 'Day 15'	System	02 Sep 2020 21:29:00

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-04T16:16:55', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5363bdb3-7858-4d39-af77-f4a015adb990'	System	04 Sep 2020 20:17:04
User entered 'No (N)'	System	04 Sep 2020 20:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-04T16:16:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5363bdb3-7858-4d39-af77-f4a015adb990'	System	04 Sep 2020 20:17:04
User entered '04 Sep 2020 16:16'	System	04 Sep 2020 20:17:04

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:29:00

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:29:00

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Sep 2020 00:55:01
User entered 'Day 16'	System	04 Sep 2020 00:55:01

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-05T18:54:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5a2eb644-3277-4e1f-a8cc-b452c157585c'	System	05 Sep 2020 22:54:21
User entered 'No (N)'	System	05 Sep 2020 22:54:21

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-05T18:54:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5a2eb644-3277-4e1f-a8cc-b452c157585c'	System	05 Sep 2020 22:54:21
User entered '05 Sep 2020 18:54'	System	05 Sep 2020 22:54:21

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 00:55:01

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 00:55:01

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Sep 2020 20:16:50
User entered 'Day 17'	System	04 Sep 2020 20:16:50

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-06T15:02:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '526e74d5-52b1-482e-9576-9ff32c093f25'	System	06 Sep 2020 19:02:19
User entered 'No (N)'	System	06 Sep 2020 19:02:19

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-06T15:02:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '526e74d5-52b1-482e-9576-9ff32c093f25'	System	06 Sep 2020 19:02:19
User entered '06 Sep 2020 15:02'	System	06 Sep 2020 19:02:19

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:16:50

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:16:50

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	05 Sep 2020 22:54:11
User entered 'Day 18'	System	05 Sep 2020 22:54:11

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-07T16:39:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f0b05e41-60f6-4026-9176-11ce7bb45375'	System	07 Sep 2020 20:39:39
User entered 'No (N)'	System	07 Sep 2020 20:39:39

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-07T16:39:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f0b05e41-60f6-4026-9176-11ce7bb45375'	System	07 Sep 2020 20:39:39
User entered '07 Sep 2020 16:39'	System	07 Sep 2020 20:39:39

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 22:54:11

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 22:54:11

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	06 Sep 2020 19:02:05
User entered 'Day 19'	System	06 Sep 2020 19:02:05

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-08T12:26:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ccfd63c5-d8c0-4bb3-890e-9f0478ab7a1c'	System	08 Sep 2020 16:26:58
User entered 'No (N)'	System	08 Sep 2020 16:26:58

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-08T12:26:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ccfd63c5-d8c0-4bb3-890e-9f0478ab7a1c'	System	08 Sep 2020 16:26:58
User entered '08 Sep 2020 12:26'	System	08 Sep 2020 16:26:58

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 19:02:05

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 19:02:05

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	07 Sep 2020 20:39:24
User entered 'Day 20'	System	07 Sep 2020 20:39:24

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-09T14:19:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1dc05e80-0e33-4e40-863d-5cb3abb2e2fe'	System	09 Sep 2020 18:19:38
User entered 'No (N)'	System	09 Sep 2020 18:19:38

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-09T14:19:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1dc05e80-0e33-4e40-863d-5cb3abb2e2fe'	System	09 Sep 2020 18:19:38
User entered '09 Sep 2020 14:19'	System	09 Sep 2020 18:19:38

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 20:39:24

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 20:39:24

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	08 Sep 2020 16:26:45
User entered 'Day 21'	System	08 Sep 2020 16:26:45

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-10T16:37:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '71eff6cc-d0bc-42ec-971d-4e48203f1810'	System	10 Sep 2020 20:37:37
User entered 'No (N)'	System	10 Sep 2020 20:37:37

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-10T16:37:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '71eff6cc-d0bc-42ec-971d-4e48203f1810'	System	10 Sep 2020 20:37:37
User entered '10 Sep 2020 16:37'	System	10 Sep 2020 20:37:37

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:26:45

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:26:45

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Sep 2020 18:19:29
User entered 'Day 22'	System	09 Sep 2020 18:19:29

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-11T13:16:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'be8b210b-864b-41d8-87c8-cc23af1f2a55'	System	11 Sep 2020 17:16:20
User entered 'No (N)'	System	11 Sep 2020 17:16:20

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-11T13:16:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'be8b210b-864b-41d8-87c8-cc23af1f2a55'	System	11 Sep 2020 17:16:20
User entered '11 Sep 2020 13:16'	System	11 Sep 2020 17:16:20

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:19:29

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:19:29

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	10 Sep 2020 20:37:26
User entered 'Day 23'	System	10 Sep 2020 20:37:26

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-12T15:47:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9d341ce2-abd0-4760-ab87-c550fd743368'	System	12 Sep 2020 19:47:14
User entered 'No (N)'	System	12 Sep 2020 19:47:14

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-12T15:47:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9d341ce2-abd0-4760-ab87-c550fd743368'	System	12 Sep 2020 19:47:14
User entered '12 Sep 2020 15:47'	System	12 Sep 2020 19:47:14

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:37:26

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:37:26

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	11 Sep 2020 17:16:08
User entered 'Day 24'	System	11 Sep 2020 17:16:08

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-13T15:17:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2ba7747e-6947-41d8-815a-50486346103c'	System	13 Sep 2020 19:17:20
User entered 'No (N)'	System	13 Sep 2020 19:17:20

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-13T15:17:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2ba7747e-6947-41d8-815a-50486346103c'	System	13 Sep 2020 19:17:20
User entered '13 Sep 2020 15:17'	System	13 Sep 2020 19:17:20

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:16:08

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:16:08

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Sep 2020 19:46:51
User entered 'Day 25'	System	12 Sep 2020 19:46:51

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-14T17:32:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '95ec4a0b-46db-429f-b53b-028293cdd34f'	System	14 Sep 2020 21:32:56
User entered 'No (N)'	System	14 Sep 2020 21:32:56

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-14T17:32:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '95ec4a0b-46db-429f-b53b-028293cdd34f'	System	14 Sep 2020 21:32:56
User entered '14 Sep 2020 17:32'	System	14 Sep 2020 21:32:56

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 19:46:51

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 19:46:51

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	13 Sep 2020 19:16:53
User entered 'Day 26'	System	13 Sep 2020 19:16:53

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-15T22:22:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '31944184-8ea2-4348-87fc-298744fa8293'	System	16 Sep 2020 02:22:49
User entered 'No (N)'	System	16 Sep 2020 02:22:49

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-15T22:22:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '31944184-8ea2-4348-87fc-298744fa8293'	System	16 Sep 2020 02:22:49
User entered '15 Sep 2020 22:22'	System	16 Sep 2020 02:22:49

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 19:16:53

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 19:16:53

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	14 Sep 2020 21:32:46
User entered 'Day 27'	System	14 Sep 2020 21:32:46

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-16T15:15:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bd0122bb-fe8a-4a27-8fa1-5e27727bfa1c'	System	16 Sep 2020 19:15:54
User entered 'No (N)'	System	16 Sep 2020 19:15:54

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-16T15:15:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bd0122bb-fe8a-4a27-8fa1-5e27727bfa1c'	System	16 Sep 2020 19:15:54
User entered '16 Sep 2020 15:15'	System	16 Sep 2020 19:15:54

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 21:32:46

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 21:32:46

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	16 Sep 2020 19:15:41
User entered 'Day 29'	System	16 Sep 2020 19:15:41

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-18T20:21:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'cae1aaac-a293-4456-bd41-ce07af6e2d51'	System	19 Sep 2020 00:21:35
User entered 'No (N)'	System	19 Sep 2020 00:21:35

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-18T20:21:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'cae1aaac-a293-4456-bd41-ce07af6e2d51'	System	19 Sep 2020 00:21:35
User entered '18 Sep 2020 20:21'	System	19 Sep 2020 00:21:35

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:15:41

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:15:41

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	18 Sep 2020 03:59:50
User entered 'Day 30'	System	18 Sep 2020 03:59:50

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-19T21:04:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0be42c60-5e28-4de9-9223-88b2a0a09b4d'	System	20 Sep 2020 01:04:12
User entered 'No (N)'	System	20 Sep 2020 01:04:12

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-19T21:04:09', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0be42c60-5e28-4de9-9223-88b2a0a09b4d'	System	20 Sep 2020 01:04:12
User entered '19 Sep 2020 21:04'	System	20 Sep 2020 01:04:12

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 03:59:50

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 03:59:50

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	19 Sep 2020 00:21:30
User entered 'Day 31'	System	19 Sep 2020 00:21:30

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-20T14:36:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '88b2862f-ba39-4fda-b17b-5a506daf516d'	System	20 Sep 2020 18:36:35
User entered 'No (N)'	System	20 Sep 2020 18:36:35

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-20T14:36:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '88b2862f-ba39-4fda-b17b-5a506daf516d'	System	20 Sep 2020 18:36:35
User entered '20 Sep 2020 14:36'	System	20 Sep 2020 18:36:35

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:21:30

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:21:30

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	20 Sep 2020 01:04:07
User entered 'Day 32'	System	20 Sep 2020 01:04:07

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-21T15:35:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2a761c4a-7cfd-4d8c-868d-60e29218627a'	System	21 Sep 2020 19:35:57
User entered 'No (N)'	System	21 Sep 2020 19:35:57

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-21T15:35:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2a761c4a-7cfd-4d8c-868d-60e29218627a'	System	21 Sep 2020 19:35:57
User entered '21 Sep 2020 15:35'	System	21 Sep 2020 19:35:57

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 01:04:07

US3672255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 01:04:07

US3672255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 21:11:30

US3672255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 10:15:57
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Visit out of window due to unsuccessful contact attempts with subject.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 21:11:49
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Sep 2020 21:11:30
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 21:11:30

US3672255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:11:30

US3672255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:11:30

US3672255

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 21:11:52

US3672255

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	02 Sep 2020 21:11:52

US3672255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4)	04 Sep 2020 18:40:43
	(b) (4), (b) (6)	

US3672255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '4 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 18:40:43

US3672255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	(b) (4), (b) (6)

US3672255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 18:40:43

US3672255

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4)	04 Sep 2020 18:40:48
	(b) (4), (b) (6)	

US3672255

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	04 Sep 2020 18:40:48

US3672255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:28:25

US3672255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '13 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:28:25

US3672255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:28:25

US3672255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:28:25

US3672255

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:28:32

US3672255

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	14 Sep 2020 18:28:32

US3672255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	22 Sep 2020 20:14:02

US3672255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '22 Sep 2020'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 20:14:02

US3672255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Clinic (Clinic)'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 20:14:02

US3672255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'VISIT2'	System	22 Sep 2020 20:14:02

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User accepted default value 'Pre-Dose (PREDOSE)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '22 Sep 2020'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '15:25'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '22 Sep 2020 15:25'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '98.9' F	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Oral (Oral)'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '97'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'bpm'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '17'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'breaths/min'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '123'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '82'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User accepted default value 'Post-Dose (POSTDOSE)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '22 Sep 2020'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '16:37'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '22 Sep 2020 16:37'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '98.9' F	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Oral (Oral)'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '94'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'bpm'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '16'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'breaths/min'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '113'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '87'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	22 Sep 2020 22:12:12

US3672255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'No (N)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:15

US3672255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	Patty Howenstine (b) (4)	22 Sep 2020 22:12:15

US3672255

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:28

US3672255

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '22 Sep 2020'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:28

US3672255

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Urine (URINE)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:28

US3672255

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Negative (NEGATIVE)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:28

US3672255

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'No (N)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:28

US3672255

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	Patty Howenstine (b) (4)	22 Sep 2020 22:12:28

US3672255

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	Patty Howenstine (b) (4)	22 Sep 2020 22:12:28

US3672255

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:24:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered empty.	System	22 Sep 2020 22:12:28

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

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)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	Patty Howenstine (b) (4)	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '22 Sep 2020'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '16:06'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '22 Sep 2020 16:06'	System	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Left Arm (LEFT ARM)'	Patty Howenstine (b) (4)	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'ONCE'	System	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 20:14:38

US3672255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:44

US3672255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '22 Sep 2020'	(b) (4) Patty Howenstine (b) (4)	22 Sep 2020 22:12:44

US3672255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '15:42'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:44

US3672255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '22 Sep 2020 15:42'	System	22 Sep 2020 22:12:44

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '22 Sep 2020'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:55

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:55

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:55

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '15:31'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:55

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '22 Sep 2020 15:31'	System	22 Sep 2020 22:12:55

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:55

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'No (N)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:55

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	Patty Howenstine (b) (4)	22 Sep 2020 22:12:55

US3672255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered empty.	System	22 Sep 2020 22:12:55

US3672255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	22 Sep 2020 22:12:58

US3672255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	22 Sep 2020 22:12:58

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2fca2b5c-95e7-43ae-a53a-e5e4aa3df701'	System	22 Sep 2020 20:39:34
User entered 'Yes (Y)'	System	22 Sep 2020 20:39:34

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2fca2b5c-95e7-43ae-a53a-e5e4aa3df701'	System	22 Sep 2020 20:39:34
User entered '98.9'	System	22 Sep 2020 20:39:34

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2fca2b5c-95e7-43ae-a53a-e5e4aa3df701'	System	22 Sep 2020 20:39:34
User entered 'No (N)'	System	22 Sep 2020 20:39:34

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2fca2b5c-95e7-43ae-a53a-e5e4aa3df701'	System	22 Sep 2020 20:39:34
User entered '22 Sep 2020 16:39'	System	22 Sep 2020 20:39:34

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 16:26'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 18:56'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:52:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '243ce287-e92e-4974-b741-605da9444a4b'	System	22 Sep 2020 23:53:04
User entered 'Yes (Y)'	System	22 Sep 2020 23:53:04

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:52:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '243ce287-e92e-4974-b741-605da9444a4b' User entered '99.3'	System	22 Sep 2020 23:53:04
	System	22 Sep 2020 23:53:04

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:52:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '243ce287-e92e-4974-b741-605da9444a4b'	System	22 Sep 2020 23:53:04
User entered 'No (N)'	System	22 Sep 2020 23:53:04

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:53:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '243ce287-e92e-4974-b741-605da9444a4b'	System	22 Sep 2020 23:53:04
User entered '22 Sep 2020 19:53'	System	22 Sep 2020 23:53:04

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 19:51'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 2'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:15:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5ed4c2e0-c3dd-47df-9270-de294665f74d'	System	23 Sep 2020 18:16:26
User entered 'Yes (Y)'	System	23 Sep 2020 18:16:26

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:16:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5ed4c2e0-c3dd-47df-9270-de294665f74d' User entered '100.9'	System	23 Sep 2020 18:16:26
	System	23 Sep 2020 18:16:26

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:16:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5ed4c2e0-c3dd-47df-9270-de294665f74d'	System	23 Sep 2020 18:16:26
User entered 'Yes (Y)'	System	23 Sep 2020 18:16:26

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmed recorded for daily pain and fever relief/prophylaxis from 22 SEP through 28 SEP 2020.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 11:04:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 19:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:16:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5ed4c2e0-c3dd-47df-9270-de294665f74d'	System	23 Sep 2020 18:16:26
User entered '1'	System	23 Sep 2020 18:16:26

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmed recorded for daily pain and fever relief/prophylaxis from 22 SEP through 28 SEP 2020' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 11:04:06
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 19:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:16:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5ed4c2e0-c3dd-47df-9270-de294665f74d'	System	23 Sep 2020 18:16:26
User entered '1'	System	23 Sep 2020 18:16:26

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:16:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5ed4c2e0-c3dd-47df-9270-de294665f74d'	System	23 Sep 2020 18:16:26
User entered '23 Sep 2020 14:16'	System	23 Sep 2020 18:16:26

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 3'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:18:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dbbfdad8-764f-4cc1-afc4-31bfe3291ae6'	System	24 Sep 2020 19:18:49
User entered 'Yes (Y)'	System	24 Sep 2020 19:18:49

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:18:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dbbfdad8-764f-4cc1-afc4-31bfe3291ae6'	System	24 Sep 2020 19:18:49
User entered '99.8'	System	24 Sep 2020 19:18:49

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:18:38', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dbbfdad8-764f-4cc1-afc4-31bfe3291ae6'	System	24 Sep 2020 19:18:49
User entered 'No (N)'	System	24 Sep 2020 19:18:49

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:18:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dbbfdad8-764f-4cc1-afc4-31bfe3291ae6'	System	24 Sep 2020 19:18:49
User entered '24 Sep 2020 15:18'	System	24 Sep 2020 19:18:49

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 4'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:14:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a8aa580d-c92a-4bcb-9ce3-8265f7b5143f'	System	25 Sep 2020 17:14:41
User entered 'Yes (Y)'	System	25 Sep 2020 17:14:41

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:14:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a8aa580d-c92a-4bcb-9ce3-8265f7b5143f' User entered '98.9'	System	25 Sep 2020 17:14:41
	System	25 Sep 2020 17:14:41

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:14:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a8aa580d-c92a-4bcb-9ce3-8265f7b5143f'	System	25 Sep 2020 17:14:41
User entered 'Yes (Y)'	System	25 Sep 2020 17:14:41

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmed recorded for daily pain and fever relief/prophylaxis from 22 SEP through 28 SEP 2020' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 11:04:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 19:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:14:34', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a8aa580d-c92a-4bcb-9ce3-8265f7b5143f'	System	25 Sep 2020 17:14:41
User entered '1'	System	25 Sep 2020 17:14:41

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmed recorded for daily pain and fever relief/prophylaxis from 22 SEP through 28 SEP 2020' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 11:05:00
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 19:54:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:14:34', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a8aa580d-c92a-4bcb-9ce3-8265f7b5143f'	System	25 Sep 2020 17:14:41
User entered '1'	System	25 Sep 2020 17:14:41

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:14:37', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a8aa580d-c92a-4bcb-9ce3-8265f7b5143f'	System	25 Sep 2020 17:14:41
User entered '25 Sep 2020 13:14'	System	25 Sep 2020 17:14:41

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 5'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:41:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '63d3c69c-839e-471a-9761-291529ba9933'	System	26 Sep 2020 22:42:23
User entered 'Yes (Y)'	System	26 Sep 2020 22:42:23

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:42:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '63d3c69c-839e-471a-9761-291529ba9933' User entered '100.0'	System	26 Sep 2020 22:42:23
	System	26 Sep 2020 22:42:23

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:42:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '63d3c69c-839e-471a-9761-291529ba9933'	System	26 Sep 2020 22:42:23
User entered 'Yes (Y)'	System	26 Sep 2020 22:42:23

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmed recorded for daily pain and fever relief/prophylaxis from 22 SEP through 28 SEP 2020' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 11:04:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 19:55:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:42:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '63d3c69c-839e-471a-9761-291529ba9933'	System	26 Sep 2020 22:42:23
User entered '1'	System	26 Sep 2020 22:42:23

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmed recorded for daily pain and fever relief/prophylaxis from 22 SEP through 28 SEP 2020' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 11:04:20
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 19:55:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:42:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '63d3c69c-839e-471a-9761-291529ba9933'	System	26 Sep 2020 22:42:23
User entered '1'	System	26 Sep 2020 22:42:23

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:42:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '63d3c69c-839e-471a-9761-291529ba9933'	System	26 Sep 2020 22:42:23
User entered '26 Sep 2020 18:42'	System	26 Sep 2020 22:42:23

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 6'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:16:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9bc5477c-e094-4a6c-af2b-5c213f1c221e'	System	27 Sep 2020 21:17:17
User entered 'Yes (Y)'	System	27 Sep 2020 21:17:17

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9bc5477c-e094-4a6c-af2b-5c213f1c221e' User entered '98.8'	System	27 Sep 2020 21:17:17
	System	27 Sep 2020 21:17:17

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9bc5477c-e094-4a6c-af2b-5c213f1c221e'	System	27 Sep 2020 21:17:17
User entered 'No (N)'	System	27 Sep 2020 21:17:17

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9bc5477c-e094-4a6c-af2b-5c213f1c221e' User entered '27 Sep 2020 17:17'	System	27 Sep 2020 21:17:17
	System	27 Sep 2020 21:17:17

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 7'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:22:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '869b4650-aa78-4e7c-8ca1-699ceac70dc3'	System	28 Sep 2020 21:22:43
User entered 'Yes (Y)'	System	28 Sep 2020 21:22:43

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:22:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '869b4650-aa78-4e7c-8ca1-699ceac70dc3'	System	28 Sep 2020 21:22:43
User entered '98.5'	System	28 Sep 2020 21:22:43

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:22:38', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '869b4650-aa78-4e7c-8ca1-699ceac70dc3'	System	28 Sep 2020 21:22:43
User entered 'No (N)'	System	28 Sep 2020 21:22:43

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:22:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '869b4650-aa78-4e7c-8ca1-699ceac70dc3'	System	28 Sep 2020 21:22:43
User entered '28 Sep 2020 17:22'	System	28 Sep 2020 21:22:43

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c8604372-b3a2-4d11-b02c-38d76cbe4d9e'	System	22 Sep 2020 20:39:54
User entered 'None (1)'	System	22 Sep 2020 20:39:54

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:38', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c8604372-b3a2-4d11-b02c-38d76cbe4d9e'	System	22 Sep 2020 20:39:54
User entered 'No (N)'	System	22 Sep 2020 20:39:54

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c8604372-b3a2-4d11-b02c-38d76cbe4d9e'	System	22 Sep 2020 20:39:54
User entered 'No (N)'	System	22 Sep 2020 20:39:54

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c8604372-b3a2-4d11-b02c-38d76cbe4d9e'	System	22 Sep 2020 20:39:54
User entered 'None (1)'	System	22 Sep 2020 20:39:54

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c8604372-b3a2-4d11-b02c-38d76cbe4d9e'	System	22 Sep 2020 20:39:54
User entered '22 Sep 2020 16:39'	System	22 Sep 2020 20:39:54

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 16:26'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 18:56'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:53:38', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e6d94ad0-ee12-4f9e-8621-563c1f50a233'	System	22 Sep 2020 23:55:19
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 23:55:19

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:53:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e6d94ad0-ee12-4f9e-8621-563c1f50a233'	System	22 Sep 2020 23:55:19
User entered 'No (N)'	System	22 Sep 2020 23:55:19

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:54:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e6d94ad0-ee12-4f9e-8621-563c1f50a233'	System	22 Sep 2020 23:55:19
User entered 'Yes (Y)'	System	22 Sep 2020 23:55:19

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e6d94ad0-ee12-4f9e-8621-563c1f50a233'	System	22 Sep 2020 23:55:19
User entered '52'	System	22 Sep 2020 23:55:19

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e6d94ad0-ee12-4f9e-8621-563c1f50a233'	System	22 Sep 2020 23:55:19
User entered 'None (1)'	System	22 Sep 2020 23:55:19

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:15', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e6d94ad0-ee12-4f9e-8621-563c1f50a233'	System	22 Sep 2020 23:55:19
User entered '22 Sep 2020 19:55'	System	22 Sep 2020 23:55:19

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 19:51'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 2'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:16:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5e6f6997-c2d7-4003-93d0-e8f5031e28a1'	System	23 Sep 2020 18:17:14
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	23 Sep 2020 18:17:14

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:16:38', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5e6f6997-c2d7-4003-93d0-e8f5031e28a1'	System	23 Sep 2020 18:17:14
User entered 'No (N)'	System	23 Sep 2020 18:17:14

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:16:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5e6f6997-c2d7-4003-93d0-e8f5031e28a1'	System	23 Sep 2020 18:17:14
User entered 'No (N)'	System	23 Sep 2020 18:17:14

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5e6f6997-c2d7-4003-93d0-e8f5031e28a1'	System	23 Sep 2020 18:17:14
User entered 'None (1)'	System	23 Sep 2020 18:17:14

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5e6f6997-c2d7-4003-93d0-e8f5031e28a1'	System	23 Sep 2020 18:17:14
User entered '23 Sep 2020 14:17'	System	23 Sep 2020 18:17:14

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 3'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:18:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4395d93a-f737-42bc-8c79-b6dc590eeaa1'	System	24 Sep 2020 19:19:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Sep 2020 19:19:08

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:18:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4395d93a-f737-42bc-8c79-b6dc590eeaa1'	System	24 Sep 2020 19:19:08
User entered 'No (N)'	System	24 Sep 2020 19:19:08

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4395d93a-f737-42bc-8c79-b6dc590eeaa1'	System	24 Sep 2020 19:19:08
User entered 'No (N)'	System	24 Sep 2020 19:19:08

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4395d93a-f737-42bc-8c79-b6dc590eeaa1'	System	24 Sep 2020 19:19:08
User entered 'None (1)'	System	24 Sep 2020 19:19:08

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4395d93a-f737-42bc-8c79-b6dc590eeaa1'	System	24 Sep 2020 19:19:08
User entered '24 Sep 2020 15:19'	System	24 Sep 2020 19:19:08

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 4'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:07:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5141c621-71ca-4a7b-9510-314ec187515d'	System	25 Sep 2020 17:07:56
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 17:07:56

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:07:34', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5141c621-71ca-4a7b-9510-314ec187515d'	System	25 Sep 2020 17:07:56
User entered 'No (N)'	System	25 Sep 2020 17:07:56

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:07:37', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5141c621-71ca-4a7b-9510-314ec187515d'	System	25 Sep 2020 17:07:56
User entered 'No (N)'	System	25 Sep 2020 17:07:56

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:07:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5141c621-71ca-4a7b-9510-314ec187515d'	System	25 Sep 2020 17:07:56
User entered 'None (1)'	System	25 Sep 2020 17:07:56

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:07:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5141c621-71ca-4a7b-9510-314ec187515d'	System	25 Sep 2020 17:07:56
User entered '25 Sep 2020 13:07'	System	25 Sep 2020 17:07:56

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 5'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:43:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '89f38d56-44fd-479e-af92-aa100d3fd7c1'	System	26 Sep 2020 22:43:22
User entered 'None (1)'	System	26 Sep 2020 22:43:22

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:43:09', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '89f38d56-44fd-479e-af92-aa100d3fd7c1'	System	26 Sep 2020 22:43:22
User entered 'No (N)'	System	26 Sep 2020 22:43:22

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:43:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '89f38d56-44fd-479e-af92-aa100d3fd7c1'	System	26 Sep 2020 22:43:22
User entered 'No (N)'	System	26 Sep 2020 22:43:22

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:43:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '89f38d56-44fd-479e-af92-aa100d3fd7c1'	System	26 Sep 2020 22:43:22
User entered 'None (1)'	System	26 Sep 2020 22:43:22

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:43:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '89f38d56-44fd-479e-af92-aa100d3fd7c1' User entered '26 Sep 2020 18:43'	System	26 Sep 2020 22:43:22
	System	26 Sep 2020 22:43:22

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 6'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '270c5112-44c7-4189-a919-727425a4aedd'	System	27 Sep 2020 21:17:45
User entered 'None (1)'	System	27 Sep 2020 21:17:45

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '270c5112-44c7-4189-a919-727425a4aedd'	System	27 Sep 2020 21:17:45
User entered 'No (N)'	System	27 Sep 2020 21:17:45

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:34', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '270c5112-44c7-4189-a919-727425a4aedd'	System	27 Sep 2020 21:17:45
User entered 'No (N)'	System	27 Sep 2020 21:17:45

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:37', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '270c5112-44c7-4189-a919-727425a4aedd'	System	27 Sep 2020 21:17:45
User entered 'None (1)'	System	27 Sep 2020 21:17:45

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:39', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '270c5112-44c7-4189-a919-727425a4aedd'	System	27 Sep 2020 21:17:45
User entered '27 Sep 2020 17:17'	System	27 Sep 2020 21:17:45

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 7'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:22:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '05671453-46ed-4849-ac4a-9b8e1c6e2582'	System	28 Sep 2020 21:23:02
User entered 'None (1)'	System	28 Sep 2020 21:23:02

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:22:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '05671453-46ed-4849-ac4a-9b8e1c6e2582'	System	28 Sep 2020 21:23:02
User entered 'No (N)'	System	28 Sep 2020 21:23:02

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:22:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '05671453-46ed-4849-ac4a-9b8e1c6e2582'	System	28 Sep 2020 21:23:02
User entered 'No (N)'	System	28 Sep 2020 21:23:02

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:22:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '05671453-46ed-4849-ac4a-9b8e1c6e2582'	System	28 Sep 2020 21:23:02
User entered 'None (1)'	System	28 Sep 2020 21:23:02

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:22:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '05671453-46ed-4849-ac4a-9b8e1c6e2582'	System	28 Sep 2020 21:23:02
User entered '28 Sep 2020 17:22'	System	28 Sep 2020 21:23:02

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:39:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4f2c5f14-9fb3-47b2-b33c-54ac9a2428f2'	System	22 Sep 2020 20:40:46
User entered 'No interference with activity (1)'	System	22 Sep 2020 20:40:46

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:40:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4f2c5f14-9fb3-47b2-b33c-54ac9a2428f2'	System	22 Sep 2020 20:40:46
User entered 'No interference with activity (1)'	System	22 Sep 2020 20:40:46

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:40:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4f2c5f14-9fb3-47b2-b33c-54ac9a2428f2'	System	22 Sep 2020 20:40:46
User entered 'None (0)'	System	22 Sep 2020 20:40:46

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:40:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4f2c5f14-9fb3-47b2-b33c-54ac9a2428f2'	System	22 Sep 2020 20:40:46
User entered 'No interference with activity (1)'	System	22 Sep 2020 20:40:46

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:40:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4f2c5f14-9fb3-47b2-b33c-54ac9a2428f2'	System	22 Sep 2020 20:40:46
User entered 'None (0)'	System	22 Sep 2020 20:40:46

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:40:18', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4f2c5f14-9fb3-47b2-b33c-54ac9a2428f2'	System	22 Sep 2020 20:40:46
User entered 'None (0)'	System	22 Sep 2020 20:40:46

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:40:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4f2c5f14-9fb3-47b2-b33c-54ac9a2428f2'	System	22 Sep 2020 20:40:46
User entered 'No (N)'	System	22 Sep 2020 20:40:46

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T16:40:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4f2c5f14-9fb3-47b2-b33c-54ac9a2428f2'	System	22 Sep 2020 20:40:46
User entered '22 Sep 2020 16:40'	System	22 Sep 2020 20:40:46

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 16:26'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 18:56'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '943b7af0-ab33-4b10-aeb9-3e80663777d6'	System	22 Sep 2020 23:55:52
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:55:52

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '943b7af0-ab33-4b10-aeb9-3e80663777d6'	System	22 Sep 2020 23:55:52
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:55:52

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '943b7af0-ab33-4b10-aeb9-3e80663777d6'	System	22 Sep 2020 23:55:52
User entered 'None (0)'	System	22 Sep 2020 23:55:52

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '943b7af0-ab33-4b10-aeb9-3e80663777d6'	System	22 Sep 2020 23:55:52
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:55:52

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:39', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '943b7af0-ab33-4b10-aeb9-3e80663777d6'	System	22 Sep 2020 23:55:52
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Sep 2020 23:55:52

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '943b7af0-ab33-4b10-aeb9-3e80663777d6'	System	22 Sep 2020 23:55:52
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:55:52

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '943b7af0-ab33-4b10-aeb9-3e80663777d6'	System	22 Sep 2020 23:55:52
User entered 'No (N)'	System	22 Sep 2020 23:55:52

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-22T19:55:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '943b7af0-ab33-4b10-aeb9-3e80663777d6'	System	22 Sep 2020 23:55:52
User entered '22 Sep 2020 19:55'	System	22 Sep 2020 23:55:52

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Sep 2020 19:51'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 2'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d7bea4f-d4c7-4642-a5db-86b3405a7511'	System	23 Sep 2020 18:17:50
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	23 Sep 2020 18:17:50

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d7bea4f-d4c7-4642-a5db-86b3405a7511'	System	23 Sep 2020 18:17:50
User entered 'Some interference with activity (2)'	System	23 Sep 2020 18:17:50

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d7bea4f-d4c7-4642-a5db-86b3405a7511'	System	23 Sep 2020 18:17:50
User entered 'Significant; prevents daily activity (3)'	System	23 Sep 2020 18:17:50

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d7bea4f-d4c7-4642-a5db-86b3405a7511'	System	23 Sep 2020 18:17:50
User entered 'Significant; prevents daily activity (3)'	System	23 Sep 2020 18:17:50

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:37', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d7bea4f-d4c7-4642-a5db-86b3405a7511'	System	23 Sep 2020 18:17:50
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Sep 2020 18:17:50

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d7bea4f-d4c7-4642-a5db-86b3405a7511'	System	23 Sep 2020 18:17:50
User entered 'No interference with activity (1)'	System	23 Sep 2020 18:17:50

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d7bea4f-d4c7-4642-a5db-86b3405a7511'	System	23 Sep 2020 18:17:50
User entered 'No (N)'	System	23 Sep 2020 18:17:50

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-23T14:17:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d7bea4f-d4c7-4642-a5db-86b3405a7511'	System	23 Sep 2020 18:17:50
User entered '23 Sep 2020 14:17'	System	23 Sep 2020 18:17:50

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 3'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '914caada-a3d3-40c3-a9b1-3660da0d9729'	System	24 Sep 2020 19:19:54
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Sep 2020 19:19:54

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '914caada-a3d3-40c3-a9b1-3660da0d9729'	System	24 Sep 2020 19:19:54
User entered 'Some interference with activity (2)'	System	24 Sep 2020 19:19:54

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '914caada-a3d3-40c3-a9b1-3660da0d9729'	System	24 Sep 2020 19:19:54
User entered 'Significant; prevents daily activity (3)'	System	24 Sep 2020 19:19:54

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:39', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '914caada-a3d3-40c3-a9b1-3660da0d9729'	System	24 Sep 2020 19:19:54
User entered 'Significant; prevents daily activity (3)'	System	24 Sep 2020 19:19:54

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '914caada-a3d3-40c3-a9b1-3660da0d9729'	System	24 Sep 2020 19:19:54
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Sep 2020 19:19:54

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '914caada-a3d3-40c3-a9b1-3660da0d9729'	System	24 Sep 2020 19:19:54
User entered 'No interference with activity (1)'	System	24 Sep 2020 19:19:54

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '914caada-a3d3-40c3-a9b1-3660da0d9729'	System	24 Sep 2020 19:19:54
User entered 'No (N)'	System	24 Sep 2020 19:19:54

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-24T15:19:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '914caada-a3d3-40c3-a9b1-3660da0d9729'	System	24 Sep 2020 19:19:54
User entered '24 Sep 2020 15:19'	System	24 Sep 2020 19:19:54

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 4'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:07:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '996fd7f7-8048-4978-9d26-f87d9b0cf40c'	System	25 Sep 2020 17:08:25
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	25 Sep 2020 17:08:25

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:07:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '996fd7f7-8048-4978-9d26-f87d9b0cf40c'	System	25 Sep 2020 17:08:25
User entered 'No interference with activity (1)'	System	25 Sep 2020 17:08:25

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:08:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '996fd7f7-8048-4978-9d26-f87d9b0cf40c'	System	25 Sep 2020 17:08:25
User entered 'Some interference with activity (2)'	System	25 Sep 2020 17:08:25

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:08:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '996fd7f7-8048-4978-9d26-f87d9b0cf40c'	System	25 Sep 2020 17:08:25
User entered 'Some interference with activity (2)'	System	25 Sep 2020 17:08:25

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:08:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '996fd7f7-8048-4978-9d26-f87d9b0cf40c'	System	25 Sep 2020 17:08:25
User entered 'None (0)'	System	25 Sep 2020 17:08:25

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:08:18', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '996fd7f7-8048-4978-9d26-f87d9b0cf40c'	System	25 Sep 2020 17:08:25
User entered 'No interference with activity (1)'	System	25 Sep 2020 17:08:25

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:08:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '996fd7f7-8048-4978-9d26-f87d9b0cf40c'	System	25 Sep 2020 17:08:25
User entered 'No (N)'	System	25 Sep 2020 17:08:25

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-25T13:08:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '996fd7f7-8048-4978-9d26-f87d9b0cf40c'	System	25 Sep 2020 17:08:25
User entered '25 Sep 2020 13:08'	System	25 Sep 2020 17:08:25

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 5'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:44:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47f9c188-24c6-4eb0-9c8e-47b6fb922b92'	System	26 Sep 2020 22:45:11
User entered 'No interference with activity (1)'	System	26 Sep 2020 22:45:11

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:44:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47f9c188-24c6-4eb0-9c8e-47b6fb922b92'	System	26 Sep 2020 22:45:11
User entered 'No interference with activity (1)'	System	26 Sep 2020 22:45:11

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:44:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47f9c188-24c6-4eb0-9c8e-47b6fb922b92'	System	26 Sep 2020 22:45:11
User entered 'No interference with activity (1)'	System	26 Sep 2020 22:45:11

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:44:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47f9c188-24c6-4eb0-9c8e-47b6fb922b92'	System	26 Sep 2020 22:45:11
User entered 'No interference with activity (1)'	System	26 Sep 2020 22:45:11

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:44:55', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47f9c188-24c6-4eb0-9c8e-47b6fb922b92'	System	26 Sep 2020 22:45:11
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Sep 2020 22:45:11

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:44:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47f9c188-24c6-4eb0-9c8e-47b6fb922b92'	System	26 Sep 2020 22:45:11
User entered 'None (0)'	System	26 Sep 2020 22:45:11

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:45:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47f9c188-24c6-4eb0-9c8e-47b6fb922b92'	System	26 Sep 2020 22:45:11
User entered 'No (N)'	System	26 Sep 2020 22:45:11

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-26T18:45:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '47f9c188-24c6-4eb0-9c8e-47b6fb922b92'	System	26 Sep 2020 22:45:11
User entered '26 Sep 2020 18:45'	System	26 Sep 2020 22:45:11

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 6'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5585cce3-4d63-46db-b792-3a4232cb1ea1'	System	27 Sep 2020 21:18:13
User entered 'No interference with activity (1)'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5585cce3-4d63-46db-b792-3a4232cb1ea1'	System	27 Sep 2020 21:18:13
User entered 'No interference with activity (1)'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5585cce3-4d63-46db-b792-3a4232cb1ea1'	System	27 Sep 2020 21:18:13
User entered 'No interference with activity (1)'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:17:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5585cce3-4d63-46db-b792-3a4232cb1ea1'	System	27 Sep 2020 21:18:13
User entered 'No interference with activity (1)'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:18:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5585cce3-4d63-46db-b792-3a4232cb1ea1'	System	27 Sep 2020 21:18:13
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:18:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5585cce3-4d63-46db-b792-3a4232cb1ea1' User entered 'None (0)'	System	27 Sep 2020 21:18:13
	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:18:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5585cce3-4d63-46db-b792-3a4232cb1ea1'	System	27 Sep 2020 21:18:13
User entered 'No (N)'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-27T17:18:09', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5585cce3-4d63-46db-b792-3a4232cb1ea1'	System	27 Sep 2020 21:18:13
User entered '27 Sep 2020 17:18'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Sep 2020 20:14:38
User entered 'Day 7'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:23:02', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7eaf1ca4-0ec4-403d-b9ff-07bc126c77c2'	System	28 Sep 2020 21:23:27
User entered 'No interference with activity (1)'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:23:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7eaf1ca4-0ec4-403d-b9ff-07bc126c77c2'	System	28 Sep 2020 21:23:27
User entered 'No interference with activity (1)'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:23:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7eaf1ca4-0ec4-403d-b9ff-07bc126c77c2'	System	28 Sep 2020 21:23:27
User entered 'None (0)'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:23:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7eaf1ca4-0ec4-403d-b9ff-07bc126c77c2'	System	28 Sep 2020 21:23:27
User entered 'No interference with activity (1)'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:23:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7eaf1ca4-0ec4-403d-b9ff-07bc126c77c2'	System	28 Sep 2020 21:23:27
User entered 'None (0)'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:23:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7eaf1ca4-0ec4-403d-b9ff-07bc126c77c2'	System	28 Sep 2020 21:23:27
User entered 'None (0)'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:23:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7eaf1ca4-0ec4-403d-b9ff-07bc126c77c2'	System	28 Sep 2020 21:23:27
User entered 'No (N)'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-28T17:23:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7eaf1ca4-0ec4-403d-b9ff-07bc126c77c2'	System	28 Sep 2020 21:23:27
User entered '28 Sep 2020 17:23'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 20:14:38

US3672255

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Sep 2020 21:18:13
User entered 'Day 8'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-29T13:58:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0e733bc8-e2a9-43b2-8de6-677cf5968d24'	System	29 Sep 2020 17:58:20
User entered 'None (0)'	System	29 Sep 2020 17:58:20

US3672255

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-29T13:58:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0e733bc8-e2a9-43b2-8de6-677cf5968d24'	System	29 Sep 2020 17:58:20
User entered '29 Sep 2020 13:58'	System	29 Sep 2020 17:58:20

US3672255

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Sep 2020 21:18:13
User entered 'Day 8'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-29T13:58:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '83b63fb6-40fd-4e9d-8b13-90e2da1248d4'	System	29 Sep 2020 17:58:26
User entered 'No interference with activity (1)'	System	29 Sep 2020 17:58:26

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-29T13:58:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '83b63fb6-40fd-4e9d-8b13-90e2da1248d4'	System	29 Sep 2020 17:58:26
User entered '29 Sep 2020 13:58'	System	29 Sep 2020 17:58:26

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	28 Sep 2020 21:23:27
User entered 'Day 9'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-30T16:42:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'df39488a-99aa-4105-a306-10f473f9239d'	System	30 Sep 2020 20:42:59
User entered 'No interference with activity (1)'	System	30 Sep 2020 20:42:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-30T16:42:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'df39488a-99aa-4105-a306-10f473f9239d'	System	30 Sep 2020 20:42:59
User entered '30 Sep 2020 16:42'	System	30 Sep 2020 20:42:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Sep 2020 17:58:26
User entered 'Day 10'	System	29 Sep 2020 17:58:26

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-01T13:42:02', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3d00508b-024d-4869-96e7-abb2f1c5b2d2'	System	01 Oct 2020 17:42:09
User entered 'No interference with activity (1)'	System	01 Oct 2020 17:42:09

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-01T13:42:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3d00508b-024d-4869-96e7-abb2f1c5b2d2'	System	01 Oct 2020 17:42:09
User entered '01 Oct 2020 13:42'	System	01 Oct 2020 17:42:09

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:58:26

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:58:26

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	30 Sep 2020 20:42:59
User entered 'Day 11'	System	30 Sep 2020 20:42:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-02T15:59:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ced61ce3-b56d-4558-94f4-c665bbb1f51d'	System	02 Oct 2020 20:00:08
User entered 'No interference with activity (1)'	System	02 Oct 2020 20:00:08

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-02T15:59:59', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ced61ce3-b56d-4558-94f4-c665bbb1f51d'	System	02 Oct 2020 20:00:08
User entered '02 Oct 2020 15:59'	System	02 Oct 2020 20:00:08

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:42:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:42:59

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	01 Oct 2020 17:42:09
User entered 'Day 12'	System	01 Oct 2020 17:42:09

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T01:38:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '51a8d3e6-9329-4793-aaf0-a7290082f724'	System	04 Oct 2020 05:38:49
User entered 'No interference with activity (1)'	System	04 Oct 2020 05:38:49

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T01:38:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '51a8d3e6-9329-4793-aaf0-a7290082f724' User entered '04 Oct 2020 01:38'	System	04 Oct 2020 05:38:49
	System	04 Oct 2020 05:38:49

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:42:09

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:42:09

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Oct 2020 20:00:08
User entered 'Day 13'	System	02 Oct 2020 20:00:08

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T15:54:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dab8637f-e339-44f0-8f02-e9382b71b039'	System	04 Oct 2020 19:54:11
User entered 'No interference with activity (1)'	System	04 Oct 2020 19:54:11

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T15:54:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dab8637f-e339-44f0-8f02-e9382b71b039'	System	04 Oct 2020 19:54:11
User entered '04 Oct 2020 15:54'	System	04 Oct 2020 19:54:11

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:00:08

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:00:08

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Oct 2020 05:38:49
User entered 'Day 14'	System	04 Oct 2020 05:38:49

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-05T19:00:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5b1b007-9fea-451f-9e67-dc41b58da2e7'	System	05 Oct 2020 23:00:20
User entered 'No interference with activity (1)'	System	05 Oct 2020 23:00:20

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-05T19:00:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5b1b007-9fea-451f-9e67-dc41b58da2e7'	System	05 Oct 2020 23:00:20
User entered '05 Oct 2020 19:00'	System	05 Oct 2020 23:00:20

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 05:38:49

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 05:38:49

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Oct 2020 19:54:11
User entered 'Day 15'	System	04 Oct 2020 19:54:11

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-06T14:09:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c3c12f4a-7ddf-4c32-8b2f-6b6bc1cebbe7'	System	06 Oct 2020 18:09:24
User entered 'Some interference with activity (2)'	System	06 Oct 2020 18:09:24

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-06T14:09:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c3c12f4a-7ddf-4c32-8b2f-6b6bc1cebbe7'	System	06 Oct 2020 18:09:24
User entered '06 Oct 2020 14:09'	System	06 Oct 2020 18:09:24

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 19:54:11

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 19:54:11

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	05 Oct 2020 23:00:20
User entered 'Day 16'	System	05 Oct 2020 23:00:20

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-07T18:09:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '43bd6aa5-2053-4773-aaa6-2596e6df62ba'	System	07 Oct 2020 22:09:17
User entered 'No interference with activity (1)'	System	07 Oct 2020 22:09:17

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-07T18:09:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '43bd6aa5-2053-4773-aaa6-2596e6df62ba'	System	07 Oct 2020 22:09:17
User entered '07 Oct 2020 18:09'	System	07 Oct 2020 22:09:17

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 23:00:20

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 23:00:20

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	06 Oct 2020 18:09:24
User entered 'Day 17'	System	06 Oct 2020 18:09:24

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-09T00:03:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5cb3f416-ac1f-435e-a522-2d7933980f8a'	System	09 Oct 2020 04:03:56
User entered 'No interference with activity (1)'	System	09 Oct 2020 04:03:56

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-09T00:03:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5cb3f416-ac1f-435e-a522-2d7933980f8a'	System	09 Oct 2020 04:03:56
User entered '09 Oct 2020 00:03'	System	09 Oct 2020 04:03:56

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:09:24

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:09:24

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	07 Oct 2020 22:09:17
User entered 'Day 18'	System	07 Oct 2020 22:09:17

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T00:07:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0363ebcd-6f39-4c24-a678-7f6b7130040c'	System	10 Oct 2020 04:07:30
User entered 'No interference with activity (1)'	System	10 Oct 2020 04:07:30

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T00:07:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0363ebcd-6f39-4c24-a678-7f6b7130040c' User entered '10 Oct 2020 00:07'	System	10 Oct 2020 04:07:30
	System	10 Oct 2020 04:07:30

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:09:17

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:09:17

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Oct 2020 04:03:56
User entered 'Day 19'	System	09 Oct 2020 04:03:56

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T15:10:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '983ae3e7-d726-4837-b2ad-fcdd52bd08ab'	System	10 Oct 2020 19:10:13
User entered 'None (0)'	System	10 Oct 2020 19:10:13

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T15:10:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '983ae3e7-d726-4837-b2ad-fcdd52bd08ab'	System	10 Oct 2020 19:10:13
User entered '10 Oct 2020 15:10'	System	10 Oct 2020 19:10:13

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 04:03:56

US3672255

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 04:03:56

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Sep 2020 21:18:13
User entered 'Day 8'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-29T13:58:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3e9bc533-e345-4a87-8de5-b7bed2a04c66'	System	29 Sep 2020 17:58:34
User entered 'No interference with activity (1)'	System	29 Sep 2020 17:58:34

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-29T13:58:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3e9bc533-e345-4a87-8de5-b7bed2a04c66'	System	29 Sep 2020 17:58:34
User entered '29 Sep 2020 13:58'	System	29 Sep 2020 17:58:34

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	28 Sep 2020 21:23:27
User entered 'Day 9'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-30T16:43:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0cd1623d-3a8d-4e01-b034-19fa7b1b27bc'	System	30 Sep 2020 20:43:10
User entered 'No interference with activity (1)'	System	30 Sep 2020 20:43:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-30T16:43:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0cd1623d-3a8d-4e01-b034-19fa7b1b27bc'	System	30 Sep 2020 20:43:10
User entered '30 Sep 2020 16:43'	System	30 Sep 2020 20:43:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Sep 2020 17:58:34
User entered 'Day 10'	System	29 Sep 2020 17:58:34

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-01T13:42:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8967ea5f-fde4-4af7-836b-ada0171ef292'	System	01 Oct 2020 17:42:16
User entered 'No interference with activity (1)'	System	01 Oct 2020 17:42:16

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-01T13:42:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8967ea5f-fde4-4af7-836b-ada0171ef292'	System	01 Oct 2020 17:42:16
User entered '01 Oct 2020 13:42'	System	01 Oct 2020 17:42:16

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:58:34

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:58:34

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	30 Sep 2020 20:43:10
User entered 'Day 11'	System	30 Sep 2020 20:43:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-02T16:00:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4d157711-ceb9-44d2-bd6b-fa7cd58cc74a'	System	02 Oct 2020 20:00:11
User entered 'No interference with activity (1)'	System	02 Oct 2020 20:00:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-02T16:00:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4d157711-ceb9-44d2-bd6b-fa7cd58cc74a'	System	02 Oct 2020 20:00:11
User entered '02 Oct 2020 16:00'	System	02 Oct 2020 20:00:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:43:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:43:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	01 Oct 2020 17:42:16
User entered 'Day 12'	System	01 Oct 2020 17:42:16

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T01:38:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bb772faa-b5e7-4045-99fd-45ec2eb5ef46'	System	04 Oct 2020 05:38:54
User entered 'No interference with activity (1)'	System	04 Oct 2020 05:38:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T01:38:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bb772faa-b5e7-4045-99fd-45ec2eb5ef46'	System	04 Oct 2020 05:38:54
User entered '04 Oct 2020 01:38'	System	04 Oct 2020 05:38:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:42:16

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:42:16

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Oct 2020 20:00:11
User entered 'Day 13'	System	02 Oct 2020 20:00:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T15:54:15', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ec645e8d-f11b-4766-b7d0-db02351faebf'	System	04 Oct 2020 19:54:21
User entered 'Some interference with activity (2)'	System	04 Oct 2020 19:54:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T15:54:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ec645e8d-f11b-4766-b7d0-db02351faebf' User entered '04 Oct 2020 15:54'	System	04 Oct 2020 19:54:21
	System	04 Oct 2020 19:54:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:00:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:00:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Oct 2020 05:38:54
User entered 'Day 14'	System	04 Oct 2020 05:38:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-05T19:00:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c3d251ab-19db-4eb2-89a8-3190d275b425'	System	05 Oct 2020 23:00:24
User entered 'No interference with activity (1)'	System	05 Oct 2020 23:00:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-05T19:00:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c3d251ab-19db-4eb2-89a8-3190d275b425'	System	05 Oct 2020 23:00:24
User entered '05 Oct 2020 19:00'	System	05 Oct 2020 23:00:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 05:38:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 05:38:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Oct 2020 19:54:21
User entered 'Day 15'	System	04 Oct 2020 19:54:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-06T14:09:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c7a8a23f-04d5-4ef6-bdbb-33ed9bf28a6f'	System	06 Oct 2020 18:09:30
User entered 'No interference with activity (1)'	System	06 Oct 2020 18:09:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-06T14:09:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c7a8a23f-04d5-4ef6-bdbb-33ed9bf28a6f' User entered '06 Oct 2020 14:09'	System	06 Oct 2020 18:09:30
	System	06 Oct 2020 18:09:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 19:54:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 19:54:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	05 Oct 2020 23:00:24
User entered 'Day 16'	System	05 Oct 2020 23:00:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-07T18:09:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '92978b09-0b9b-4368-b955-73bbb762b014'	System	07 Oct 2020 22:09:25
User entered 'No interference with activity (1)'	System	07 Oct 2020 22:09:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-07T18:09:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '92978b09-0b9b-4368-b955-73bbb762b014' User entered '07 Oct 2020 18:09'	System	07 Oct 2020 22:09:25
	System	07 Oct 2020 22:09:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 23:00:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 23:00:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	06 Oct 2020 18:09:30
User entered 'Day 17'	System	06 Oct 2020 18:09:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-09T00:03:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3d639984-ebfc-45ed-882d-8c289793a9c2'	System	09 Oct 2020 04:04:03
User entered 'No interference with activity (1)'	System	09 Oct 2020 04:04:03

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-09T00:03:59', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3d639984-ebfc-45ed-882d-8c289793a9c2'	System	09 Oct 2020 04:04:03
User entered '09 Oct 2020 00:03'	System	09 Oct 2020 04:04:03

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:09:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:09:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	07 Oct 2020 22:09:25
User entered 'Day 18'	System	07 Oct 2020 22:09:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T00:07:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '14a8a0f6-dd2e-4c36-870c-320e12584325'	System	10 Oct 2020 04:07:40
User entered 'No interference with activity (1)'	System	10 Oct 2020 04:07:40

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T00:07:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '14a8a0f6-dd2e-4c36-870c-320e12584325'	System	10 Oct 2020 04:07:40
User entered '10 Oct 2020 00:07'	System	10 Oct 2020 04:07:40

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:09:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:09:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Oct 2020 04:04:03
User entered 'Day 19'	System	09 Oct 2020 04:04:03

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T15:10:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64e19be9-ca0e-4fe9-b83b-5a39f911732e'	System	10 Oct 2020 19:10:27
User entered 'No interference with activity (1)'	System	10 Oct 2020 19:10:27

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T15:10:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '64e19be9-ca0e-4fe9-b83b-5a39f911732e'	System	10 Oct 2020 19:10:27
User entered '10 Oct 2020 15:10'	System	10 Oct 2020 19:10:27

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 04:04:03

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 04:04:03

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	10 Oct 2020 04:07:40
User entered 'Day 20'	System	10 Oct 2020 04:07:40

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-11T23:59:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '67a8e236-4386-4683-9b0a-c4882157c6da'	System	12 Oct 2020 03:59:53
User entered 'Some interference with activity (2)'	System	12 Oct 2020 03:59:53

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-11T23:59:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '67a8e236-4386-4683-9b0a-c4882157c6da'	System	12 Oct 2020 03:59:53
User entered '11 Oct 2020 23:59'	System	12 Oct 2020 03:59:53

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 04:07:40

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 04:07:40

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	10 Oct 2020 19:10:27
User entered 'Day 21'	System	10 Oct 2020 19:10:27

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-12T16:44:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c08aad1c-35fc-407f-b94d-4c4da3c926b5'	System	12 Oct 2020 20:44:37
User entered 'No interference with activity (1)'	System	12 Oct 2020 20:44:37

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-12T16:44:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c08aad1c-35fc-407f-b94d-4c4da3c926b5'	System	12 Oct 2020 20:44:37
User entered '12 Oct 2020 16:44'	System	12 Oct 2020 20:44:37

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 19:10:27

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 19:10:27

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Oct 2020 03:59:53
User entered 'Day 22'	System	12 Oct 2020 03:59:53

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-13T16:16:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ef0ac0e5-e370-4b1d-8f77-bd9239056032'	System	13 Oct 2020 20:16:59
User entered 'Some interference with activity (2)'	System	13 Oct 2020 20:16:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-13T16:16:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ef0ac0e5-e370-4b1d-8f77-bd9239056032'	System	13 Oct 2020 20:16:59
User entered '13 Oct 2020 16:16'	System	13 Oct 2020 20:16:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 03:59:53

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 03:59:53

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Oct 2020 20:44:37
User entered 'Day 23'	System	12 Oct 2020 20:44:37

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-14T12:07:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'eeb70d4b-43a2-4b70-b838-26ad91cfa99f'	System	14 Oct 2020 16:07:25
User entered 'No interference with activity (1)'	System	14 Oct 2020 16:07:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-14T12:07:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'eeb70d4b-43a2-4b70-b838-26ad91cfa99f'	System	14 Oct 2020 16:07:25
User entered '14 Oct 2020 12:07'	System	14 Oct 2020 16:07:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:44:37

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:44:37

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	13 Oct 2020 20:16:59
User entered 'Day 24'	System	13 Oct 2020 20:16:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-15T15:11:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'db817dfe-ae09-47c8-a3bc-8cee244c65df'	System	15 Oct 2020 19:11:10
User entered 'No interference with activity (1)'	System	15 Oct 2020 19:11:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-15T15:11:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'db817dfe-ae09-47c8-a3bc-8cee244c65df'	System	15 Oct 2020 19:11:10
User entered '15 Oct 2020 15:11'	System	15 Oct 2020 19:11:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:16:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:16:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	14 Oct 2020 16:07:25
User entered 'Day 25'	System	14 Oct 2020 16:07:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-16T12:58:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f728ae48-b158-4581-ac3f-6cf4716b80b5'	System	16 Oct 2020 16:58:54
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:58:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-16T12:58:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f728ae48-b158-4581-ac3f-6cf4716b80b5'	System	16 Oct 2020 16:58:54
User entered '16 Oct 2020 12:58'	System	16 Oct 2020 16:58:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:07:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:07:25

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	15 Oct 2020 19:11:10
User entered 'Day 26'	System	15 Oct 2020 19:11:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-17T16:21:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2540195a-4890-4730-b2ee-656a0d279f68'	System	17 Oct 2020 20:21:36
User entered 'No interference with activity (1)'	System	17 Oct 2020 20:21:36

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-17T16:21:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2540195a-4890-4730-b2ee-656a0d279f68'	System	17 Oct 2020 20:21:36
User entered '17 Oct 2020 16:21'	System	17 Oct 2020 20:21:36

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:11:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:11:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	16 Oct 2020 16:58:54
User entered 'Day 27'	System	16 Oct 2020 16:58:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-18T14:23:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b6d37f53-6186-464f-b957-2efd7709171e'	System	18 Oct 2020 18:23:12
User entered 'No interference with activity (1)'	System	18 Oct 2020 18:23:12

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-18T14:23:09', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b6d37f53-6186-464f-b957-2efd7709171e' User entered '18 Oct 2020 14:23'	System	18 Oct 2020 18:23:12
	System	18 Oct 2020 18:23:12

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 16:58:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 16:58:54

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	17 Oct 2020 20:21:36
User entered 'Day 28'	System	17 Oct 2020 20:21:36

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-20T00:00:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '803b940d-8f41-4366-bf69-d85a2efda4ca'	System	20 Oct 2020 04:00:59
User entered 'No interference with activity (1)'	System	20 Oct 2020 04:00:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-20T00:00:55', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '803b940d-8f41-4366-bf69-d85a2efda4ca'	System	20 Oct 2020 04:00:59
User entered '20 Oct 2020 00:00'	System	20 Oct 2020 04:00:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 20:21:36

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(28)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 20:21:36

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	18 Oct 2020 18:23:12
User entered 'Day 29'	System	18 Oct 2020 18:23:12

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-20T12:59:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '23cfd41b-790d-4849-9bb7-7d46170ea50e'	System	20 Oct 2020 16:59:46
User entered 'Some interference with activity (2)'	System	20 Oct 2020 16:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-20T12:59:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '23cfd41b-790d-4849-9bb7-7d46170ea50e'	System	20 Oct 2020 16:59:46
User entered '20 Oct 2020 12:59'	System	20 Oct 2020 16:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 18:23:12

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 18:23:12

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	20 Oct 2020 04:00:59
User entered 'Day 30'	System	20 Oct 2020 04:00:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-21T21:33:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ce1c8692-cfe7-4005-9de2-745448266333'	System	22 Oct 2020 01:34:04
User entered 'Some interference with activity (2)'	System	22 Oct 2020 01:34:04

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-21T21:33:59', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ce1c8692-cfe7-4005-9de2-745448266333'	System	22 Oct 2020 01:34:04
User entered '21 Oct 2020 21:33'	System	22 Oct 2020 01:34:04

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 04:00:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 04:00:59

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	20 Oct 2020 16:59:46
User entered 'Day 31'	System	20 Oct 2020 16:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-22T18:21:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9b2fd3fb-5775-482c-8b63-435ee980df08'	System	22 Oct 2020 22:21:51
User entered 'No interference with activity (1)'	System	22 Oct 2020 22:21:51

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-22T18:21:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9b2fd3fb-5775-482c-8b63-435ee980df08'	System	22 Oct 2020 22:21:51
User entered '22 Oct 2020 18:21'	System	22 Oct 2020 22:21:51

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Oct 2020 01:34:04
User entered 'Day 32'	System	22 Oct 2020 01:34:04

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-23T15:52:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4e07690a-4d01-4278-9984-60006090d6c1'	System	23 Oct 2020 19:52:11
User entered 'Some interference with activity (2)'	System	23 Oct 2020 19:52:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-23T15:52:09', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4e07690a-4d01-4278-9984-60006090d6c1'	System	23 Oct 2020 19:52:11
User entered '23 Oct 2020 15:52'	System	23 Oct 2020 19:52:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 01:34:04

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 01:34:04

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Oct 2020 22:21:51
User entered 'Day 33'	System	22 Oct 2020 22:21:51

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-24T21:21:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '26b474d7-5e67-48c4-9268-b7dc07aa01d7'	System	25 Oct 2020 01:21:35
User entered 'No interference with activity (1)'	System	25 Oct 2020 01:21:35

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-24T21:21:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '26b474d7-5e67-48c4-9268-b7dc07aa01d7'	System	25 Oct 2020 01:21:35
User entered '24 Oct 2020 21:21'	System	25 Oct 2020 01:21:35

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 22:21:51

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(33)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 22:21:51

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	23 Oct 2020 19:52:11
User entered 'Day 34'	System	23 Oct 2020 19:52:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-25T16:49:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2fa136a7-6dda-4dbc-85cf-441040801bf9'	System	25 Oct 2020 20:49:10
User entered 'No interference with activity (1)'	System	25 Oct 2020 20:49:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-25T16:49:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2fa136a7-6dda-4dbc-85cf-441040801bf9'	System	25 Oct 2020 20:49:10
User entered '25 Oct 2020 16:49'	System	25 Oct 2020 20:49:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 19:52:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(34)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 19:52:11

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	25 Oct 2020 01:21:35
User entered 'Day 35'	System	25 Oct 2020 01:21:35

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-26T15:18:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3f3ee80e-047a-423b-abb0-e9deabbd57db'	System	26 Oct 2020 19:18:07
User entered 'Some interference with activity (2)'	System	26 Oct 2020 19:18:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-26T15:18:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3f3ee80e-047a-423b-abb0-e9deabbd57db'	System	26 Oct 2020 19:18:07
User entered '26 Oct 2020 15:18'	System	26 Oct 2020 19:18:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 01:21:35

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(35)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 01:21:35

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	25 Oct 2020 20:49:10
User entered 'Day 36'	System	25 Oct 2020 20:49:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-27T13:14:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '99b4ed40-c7ac-441e-8727-a1e8933aee8a'	System	27 Oct 2020 17:14:55
User entered 'Some interference with activity (2)'	System	27 Oct 2020 17:14:55

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-27T13:14:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '99b4ed40-c7ac-441e-8727-a1e8933aee8a'	System	27 Oct 2020 17:14:55
User entered '27 Oct 2020 13:14'	System	27 Oct 2020 17:14:55

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 20:49:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(36)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 20:49:10

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	26 Oct 2020 19:18:07
User entered 'Day 37'	System	26 Oct 2020 19:18:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-28T13:14:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a161a087-8c5f-4089-9f9c-26575cde821a'	System	28 Oct 2020 17:14:28
User entered 'No interference with activity (1)'	System	28 Oct 2020 17:14:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-28T13:14:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a161a087-8c5f-4089-9f9c-26575cde821a'	System	28 Oct 2020 17:14:28
User entered '28 Oct 2020 13:14'	System	28 Oct 2020 17:14:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 19:18:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(37)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 19:18:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Oct 2020 17:14:55
User entered 'Day 38'	System	27 Oct 2020 17:14:55

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-29T12:11:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4b876bb4-011a-47ce-86a9-54587d6df34d'	System	29 Oct 2020 16:11:30
User entered 'No interference with activity (1)'	System	29 Oct 2020 16:11:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-29T12:11:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4b876bb4-011a-47ce-86a9-54587d6df34d'	System	29 Oct 2020 16:11:30
User entered '29 Oct 2020 12:11'	System	29 Oct 2020 16:11:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:14:55

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(38)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:14:55

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	28 Oct 2020 17:14:28
User entered 'Day 39'	System	28 Oct 2020 17:14:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-30T19:41:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '87d23a6a-4932-4f72-b5e9-f30cd3117490'	System	30 Oct 2020 23:41:52
User entered 'Some interference with activity (2)'	System	30 Oct 2020 23:41:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-30T19:41:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '87d23a6a-4932-4f72-b5e9-f30cd3117490'	System	30 Oct 2020 23:41:52
User entered '30 Oct 2020 19:41'	System	30 Oct 2020 23:41:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 17:14:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(39)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 17:14:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Oct 2020 16:11:30
User entered 'Day 40'	System	29 Oct 2020 16:11:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-31T12:08:39', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f05e476c-227e-41c2-8f66-a5cb6457f871'	System	31 Oct 2020 16:08:44
User entered 'No interference with activity (1)'	System	31 Oct 2020 16:08:44

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-31T12:08:41', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f05e476c-227e-41c2-8f66-a5cb6457f871'	System	31 Oct 2020 16:08:44
User entered '31 Oct 2020 12:08'	System	31 Oct 2020 16:08:44

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 16:11:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(40)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 16:11:30

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	30 Oct 2020 23:41:52
User entered 'Day 41'	System	30 Oct 2020 23:41:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-01T23:59:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '31ae1b4f-12bd-47af-95aa-a087470ed862'	System	02 Nov 2020 04:59:50
User entered 'No interference with activity (1)'	System	02 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-01T23:59:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '31ae1b4f-12bd-47af-95aa-a087470ed862'	System	02 Nov 2020 04:59:50
User entered '01 Nov 2020 23:59'	System	02 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 23:41:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(41)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 23:41:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	31 Oct 2020 16:08:44
User entered 'Day 42'	System	31 Oct 2020 16:08:44

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-02T12:32:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0f6edbfd-d748-43bd-a1f8-03bb2f438d83'	System	02 Nov 2020 17:32:08
User entered 'No interference with activity (1)'	System	02 Nov 2020 17:32:08

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-02T12:32:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0f6edbfd-d748-43bd-a1f8-03bb2f438d83'	System	02 Nov 2020 17:32:08
User entered '02 Nov 2020 12:32'	System	02 Nov 2020 17:32:08

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 16:08:44

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(42)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 16:08:44

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Nov 2020 04:59:50
User entered 'Day 43'	System	02 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-03T12:14:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bbb9b7d2-7dbe-4f8b-82ca-46b8228e5781'	System	03 Nov 2020 17:14:07
User entered 'No interference with activity (1)'	System	03 Nov 2020 17:14:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-03T12:14:02', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bbb9b7d2-7dbe-4f8b-82ca-46b8228e5781' User entered '03 Nov 2020 12:14'	System	03 Nov 2020 17:14:07
	System	03 Nov 2020 17:14:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(43)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Nov 2020 17:32:08
User entered 'Day 44'	System	02 Nov 2020 17:32:08

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-04T14:52:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3dfc5089-8144-4b55-9a9d-ea6f0f9f838a'	System	04 Nov 2020 19:52:50
User entered 'No interference with activity (1)'	System	04 Nov 2020 19:52:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-04T14:52:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3dfc5089-8144-4b55-9a9d-ea6f0f9f838a'	System	04 Nov 2020 19:52:50
User entered '04 Nov 2020 14:52'	System	04 Nov 2020 19:52:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 17:32:08

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(44)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 17:32:08

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	03 Nov 2020 17:14:07
User entered 'Day 45'	System	03 Nov 2020 17:14:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-05T14:12:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b3bab716-4812-4499-8bdb-1c433b92cb0e'	System	05 Nov 2020 19:12:07
User entered 'No interference with activity (1)'	System	05 Nov 2020 19:12:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-05T14:12:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b3bab716-4812-4499-8bdb-1c433b92cb0e'	System	05 Nov 2020 19:12:07
User entered '05 Nov 2020 14:12'	System	05 Nov 2020 19:12:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 17:14:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(45)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 17:14:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Nov 2020 19:52:50
User entered 'Day 46'	System	04 Nov 2020 19:52:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-06T23:59:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1daf021e-0692-41e8-ac93-7a8a95e28ee3'	System	07 Nov 2020 04:59:52
User entered 'No interference with activity (1)'	System	07 Nov 2020 04:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-06T23:59:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1daf021e-0692-41e8-ac93-7a8a95e28ee3'	System	07 Nov 2020 04:59:52
User entered '06 Nov 2020 23:59'	System	07 Nov 2020 04:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 19:52:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(46)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 19:52:50

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	05 Nov 2020 19:12:07
User entered 'Day 47'	System	05 Nov 2020 19:12:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-07T23:59:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '27a4ba93-2fef-40ee-b945-050ab6f14214'	System	08 Nov 2020 04:59:46
User entered 'No interference with activity (1)'	System	08 Nov 2020 04:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-07T23:59:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '27a4ba93-2fef-40ee-b945-050ab6f14214'	System	08 Nov 2020 04:59:46
User entered '07 Nov 2020 23:59'	System	08 Nov 2020 04:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 19:12:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(47)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 19:12:07

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	07 Nov 2020 04:59:52
User entered 'Day 48'	System	07 Nov 2020 04:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-09T00:25:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '819601cd-aefd-4465-94b6-95ea4c85cd59'	System	09 Nov 2020 05:25:21
User entered 'No interference with activity (1)'	System	09 Nov 2020 05:25:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-09T00:25:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '819601cd-aefd-4465-94b6-95ea4c85cd59'	System	09 Nov 2020 05:25:21
User entered '09 Nov 2020 00:25'	System	09 Nov 2020 05:25:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Nov 2020 12:00'	System	07 Nov 2020 04:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(48)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Nov 2020 11:59'	System	07 Nov 2020 04:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	08 Nov 2020 04:59:46
User entered 'Day 49'	System	08 Nov 2020 04:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-09T13:13:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'fd798fac-707c-4bfd-bd65-e795db697371'	System	09 Nov 2020 18:13:05
User entered 'No interference with activity (1)'	System	09 Nov 2020 18:13:05

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-09T13:13:02', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'fd798fac-707c-4bfd-bd65-e795db697371'	System	09 Nov 2020 18:13:05
User entered '09 Nov 2020 13:13'	System	09 Nov 2020 18:13:05

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Nov 2020 12:00'	System	08 Nov 2020 04:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(49)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Nov 2020 11:59'	System	08 Nov 2020 04:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Nov 2020 05:25:21
User entered 'Day 50'	System	09 Nov 2020 05:25:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-10T23:59:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '810fb62c-8828-47d7-ba90-a28e1c665a75'	System	11 Nov 2020 04:59:49
User entered 'No interference with activity (1)'	System	11 Nov 2020 04:59:49

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-10T23:59:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '810fb62c-8828-47d7-ba90-a28e1c665a75'	System	11 Nov 2020 04:59:49
User entered '10 Nov 2020 23:59'	System	11 Nov 2020 04:59:49

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Nov 2020 12:00'	System	09 Nov 2020 05:25:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(50)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Nov 2020 11:59'	System	09 Nov 2020 05:25:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Nov 2020 18:13:05
User entered 'Day 51'	System	09 Nov 2020 18:13:05

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-12T00:31:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b39cbb07-c861-4681-8f7a-e11a34e7154c'	System	12 Nov 2020 05:31:24
User entered 'Some interference with activity (2)'	System	12 Nov 2020 05:31:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-12T00:31:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b39cbb07-c861-4681-8f7a-e11a34e7154c'	System	12 Nov 2020 05:31:24
User entered '12 Nov 2020 00:31'	System	12 Nov 2020 05:31:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Nov 2020 12:00'	System	09 Nov 2020 18:13:05

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(51)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Nov 2020 11:59'	System	09 Nov 2020 18:13:05

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	11 Nov 2020 04:59:49
User entered 'Day 52'	System	11 Nov 2020 04:59:49

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-12T12:49:16', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e7219b10-e95e-4faa-91d1-5ad1b1772807'	System	12 Nov 2020 17:49:26
User entered 'Some interference with activity (2)'	System	12 Nov 2020 17:49:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-12T12:49:19', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e7219b10-e95e-4faa-91d1-5ad1b1772807'	System	12 Nov 2020 17:49:26
User entered '12 Nov 2020 12:49'	System	12 Nov 2020 17:49:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 04:59:49

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(52)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 04:59:49

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Nov 2020 05:31:24
User entered 'Day 53'	System	12 Nov 2020 05:31:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-13T12:00:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '169c4cbd-e270-45f4-a5fd-0ed6be0e60e7'	System	13 Nov 2020 17:01:32
User entered 'No interference with activity (1)'	System	13 Nov 2020 17:01:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-13T12:00:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '169c4cbd-e270-45f4-a5fd-0ed6be0e60e7'	System	13 Nov 2020 17:01:32
User entered '13 Nov 2020 12:00'	System	13 Nov 2020 17:01:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 05:31:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(53)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 05:31:24

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Nov 2020 17:49:26
User entered 'Day 54'	System	12 Nov 2020 17:49:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-14T18:14:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b455d679-b5c7-4d87-bd79-75bffa95fac'	System	14 Nov 2020 23:14:48
User entered 'Some interference with activity (2)'	System	14 Nov 2020 23:14:48

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-14T18:14:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b455d679-b5c7-4d87-bd79-75bffa95fac'	System	14 Nov 2020 23:14:48
User entered '14 Nov 2020 18:14'	System	14 Nov 2020 23:14:48

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 17:49:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(54)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 17:49:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	13 Nov 2020 17:01:32
User entered 'Day 55'	System	13 Nov 2020 17:01:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-15T17:05:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b1f9b22c-6864-43eb-8f97-625ccbe768a7'	System	15 Nov 2020 22:05:29
User entered 'Some interference with activity (2)'	System	15 Nov 2020 22:05:29

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-15T17:05:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b1f9b22c-6864-43eb-8f97-625ccbe768a7'	System	15 Nov 2020 22:05:29
User entered '15 Nov 2020 17:05'	System	15 Nov 2020 22:05:29

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Nov 2020 12:00'	System	13 Nov 2020 17:01:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(55)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Nov 2020 11:59'	System	13 Nov 2020 17:01:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	14 Nov 2020 23:14:48
User entered 'Day 56'	System	14 Nov 2020 23:14:48

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-16T12:12:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bc878090-778c-42ae-aa75-4c2acb1d2ca1'	System	16 Nov 2020 17:12:26
User entered 'No interference with activity (1)'	System	16 Nov 2020 17:12:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-16T12:12:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bc878090-778c-42ae-aa75-4c2acb1d2ca1'	System	16 Nov 2020 17:12:26
User entered '16 Nov 2020 12:12'	System	16 Nov 2020 17:12:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Nov 2020 12:00'	System	14 Nov 2020 23:14:48

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(56)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Nov 2020 11:59'	System	14 Nov 2020 23:14:48

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	15 Nov 2020 22:05:29
User entered 'Day 57'	System	15 Nov 2020 22:05:29

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-17T12:00:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '49f277d8-773d-47a9-a813-77000ab74676'	System	17 Nov 2020 17:00:32
User entered 'No interference with activity (1)'	System	17 Nov 2020 17:00:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-17T12:00:18', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '49f277d8-773d-47a9-a813-77000ab74676'	System	17 Nov 2020 17:00:32
User entered '17 Nov 2020 12:00'	System	17 Nov 2020 17:00:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 22:05:29

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(57)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 22:05:29

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	16 Nov 2020 17:12:26
User entered 'Day 58'	System	16 Nov 2020 17:12:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:31:15', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '38f3a94c-32e3-4d6f-b87a-276271c35364'	System	18 Nov 2020 17:31:21
User entered 'No interference with activity (1)'	System	18 Nov 2020 17:31:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:31:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '38f3a94c-32e3-4d6f-b87a-276271c35364'	System	18 Nov 2020 17:31:21
User entered '18 Nov 2020 12:31'	System	18 Nov 2020 17:31:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 17:12:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(58)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 17:12:26

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	17 Nov 2020 17:00:32
User entered 'Day 59'	System	17 Nov 2020 17:00:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-19T12:05:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '66559794-4496-4f7a-9061-57a17a6f67c6'	System	19 Nov 2020 17:05:28
User entered 'Some interference with activity (2)'	System	19 Nov 2020 17:05:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-19T12:05:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '66559794-4496-4f7a-9061-57a17a6f67c6'	System	19 Nov 2020 17:05:28
User entered '19 Nov 2020 12:05'	System	19 Nov 2020 17:05:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Nov 2020 12:00'	System	17 Nov 2020 17:00:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(59)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Nov 2020 11:59'	System	17 Nov 2020 17:00:32

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	18 Nov 2020 17:31:21
User entered 'Day 60'	System	18 Nov 2020 17:31:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-20T21:03:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '077f7bff-009d-491b-b306-8b206e5be974'	System	21 Nov 2020 02:03:47
User entered 'Some interference with activity (2)'	System	21 Nov 2020 02:03:47

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-20T21:03:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '077f7bff-009d-491b-b306-8b206e5be974'	System	21 Nov 2020 02:03:47
User entered '20 Nov 2020 21:03'	System	21 Nov 2020 02:03:47

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 17:31:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(60)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 17:31:21

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	19 Nov 2020 17:05:28
User entered 'Day 61'	System	19 Nov 2020 17:05:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 17:05:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(61)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 17:05:28

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Nov 2020 02:03:47
User entered 'Day 62'	System	21 Nov 2020 02:03:47

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 02:03:47

US3672255

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(62)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 02:03:47

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Sep 2020 21:18:13
User entered 'Day 8'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-29T13:58:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f38648c7-5eb5-4877-81b2-f5f8135b59d9'	System	29 Sep 2020 17:58:38
User entered 'No (N)'	System	29 Sep 2020 17:58:38

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-29T13:58:34', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f38648c7-5eb5-4877-81b2-f5f8135b59d9'	System	29 Sep 2020 17:58:38
User entered '29 Sep 2020 13:58'	System	29 Sep 2020 17:58:38

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 21:18:13

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	28 Sep 2020 21:23:27
User entered 'Day 9'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-30T16:43:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9d65ddc4-13b5-4935-bffb-148561ee9e96'	System	30 Sep 2020 20:43:17
User entered 'No (N)'	System	30 Sep 2020 20:43:17

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-09-30T16:43:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9d65ddc4-13b5-4935-bffb-148561ee9e96'	System	30 Sep 2020 20:43:17
User entered '30 Sep 2020 16:43'	System	30 Sep 2020 20:43:17

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:23:27

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Sep 2020 17:58:26
User entered 'Day 10'	System	29 Sep 2020 17:58:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-01T13:42:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '50696a98-08f3-4326-b55b-9546cdc804ba'	System	01 Oct 2020 17:42:22
User entered 'No (N)'	System	01 Oct 2020 17:42:22

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-01T13:42:15', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '50696a98-08f3-4326-b55b-9546cdc804ba'	System	01 Oct 2020 17:42:22
User entered '01 Oct 2020 13:42'	System	01 Oct 2020 17:42:22

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 17:58:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 17:58:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	30 Sep 2020 20:42:59
User entered 'Day 11'	System	30 Sep 2020 20:42:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-02T16:00:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8cf7b133-e06c-44ed-8dc0-205c15417da9'	System	02 Oct 2020 20:00:18
User entered 'No (N)'	System	02 Oct 2020 20:00:18

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-02T16:00:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8cf7b133-e06c-44ed-8dc0-205c15417da9'	System	02 Oct 2020 20:00:18
User entered '02 Oct 2020 16:00'	System	02 Oct 2020 20:00:18

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:42:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:42:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	01 Oct 2020 17:42:09
User entered 'Day 12'	System	01 Oct 2020 17:42:09

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T01:38:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '13274793-8370-4398-984a-5b62f1e3f44d'	System	04 Oct 2020 05:38:59
User entered 'No (N)'	System	04 Oct 2020 05:38:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T01:38:55', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '13274793-8370-4398-984a-5b62f1e3f44d'	System	04 Oct 2020 05:38:59
User entered '04 Oct 2020 01:38'	System	04 Oct 2020 05:38:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:42:09

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:42:09

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Oct 2020 20:00:08
User entered 'Day 13'	System	02 Oct 2020 20:00:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T15:54:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '924f4e75-37fc-4cef-9e86-6b244a45dc75'	System	04 Oct 2020 19:54:28
User entered 'No (N)'	System	04 Oct 2020 19:54:28

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-04T15:54:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '924f4e75-37fc-4cef-9e86-6b244a45dc75'	System	04 Oct 2020 19:54:28
User entered '04 Oct 2020 15:54'	System	04 Oct 2020 19:54:28

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:00:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:00:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Oct 2020 05:38:49
User entered 'Day 14'	System	04 Oct 2020 05:38:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-05T19:00:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bd12c218-fc10-4893-8a31-d5bdba59849f'	System	05 Oct 2020 23:00:31
User entered 'No (N)'	System	05 Oct 2020 23:00:31

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-05T19:00:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'bd12c218-fc10-4893-8a31-d5bdba59849f'	System	05 Oct 2020 23:00:31
User entered '05 Oct 2020 19:00'	System	05 Oct 2020 23:00:31

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 05:38:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 05:38:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Oct 2020 19:54:11
User entered 'Day 15'	System	04 Oct 2020 19:54:11

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-06T14:09:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1e9cb1a7-e22f-42c2-885d-a4b9403c5193'	System	06 Oct 2020 18:09:37
User entered 'No (N)'	System	06 Oct 2020 18:09:37

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-06T14:09:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1e9cb1a7-e22f-42c2-885d-a4b9403c5193'	System	06 Oct 2020 18:09:37
User entered '06 Oct 2020 14:09'	System	06 Oct 2020 18:09:37

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 19:54:11

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 19:54:11

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	05 Oct 2020 23:00:20
User entered 'Day 16'	System	05 Oct 2020 23:00:20

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-07T18:09:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '15afad1f-8634-4760-8005-d30c78521be4'	System	07 Oct 2020 22:09:35
User entered 'No (N)'	System	07 Oct 2020 22:09:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-07T18:09:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '15afad1f-8634-4760-8005-d30c78521be4'	System	07 Oct 2020 22:09:35
User entered '07 Oct 2020 18:09'	System	07 Oct 2020 22:09:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 23:00:20

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 23:00:20

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	06 Oct 2020 18:09:24
User entered 'Day 17'	System	06 Oct 2020 18:09:24

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-09T00:04:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '66fa8e35-992d-410e-a299-bc84e9cf618b'	System	09 Oct 2020 04:04:10
User entered 'No (N)'	System	09 Oct 2020 04:04:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-09T00:04:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '66fa8e35-992d-410e-a299-bc84e9cf618b'	System	09 Oct 2020 04:04:10
User entered '09 Oct 2020 00:04'	System	09 Oct 2020 04:04:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:09:24

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:09:24

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	07 Oct 2020 22:09:17
User entered 'Day 18'	System	07 Oct 2020 22:09:17

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T00:07:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '041a3f40-218a-450c-ac72-c83e26fb3412'	System	10 Oct 2020 04:07:49
User entered 'No (N)'	System	10 Oct 2020 04:07:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T00:07:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '041a3f40-218a-450c-ac72-c83e26fb3412'	System	10 Oct 2020 04:07:49
User entered '10 Oct 2020 00:07'	System	10 Oct 2020 04:07:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:09:17

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:09:17

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Oct 2020 04:03:56
User entered 'Day 19'	System	09 Oct 2020 04:03:56

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T15:10:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e5918594-0845-465f-8ba8-999527442217'	System	10 Oct 2020 19:10:31
User entered 'No (N)'	System	10 Oct 2020 19:10:31

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-10T15:10:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e5918594-0845-465f-8ba8-999527442217'	System	10 Oct 2020 19:10:31
User entered '10 Oct 2020 15:10'	System	10 Oct 2020 19:10:31

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 04:03:56

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 04:03:56

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
DataPoint Activated.	System	10 Oct 2020 19:10:27
DataPoint Inactivated.	System	10 Oct 2020 19:10:13
Data entry locked.	System	10 Oct 2020 04:07:30
User entered 'Day 20'	System	10 Oct 2020 04:07:30

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-11T23:59:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4ce94236-caf4-4ba2-8979-47873a1982d5'	System	12 Oct 2020 03:59:56
User entered 'No (N)'	System	12 Oct 2020 03:59:56
DataPoint Activated.	System	10 Oct 2020 19:10:27
DataPoint Inactivated.	System	10 Oct 2020 19:10:13

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-11T23:59:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4ce94236-caf4-4ba2-8979-47873a1982d5'	System	12 Oct 2020 03:59:56
User entered '11 Oct 2020 23:59'	System	12 Oct 2020 03:59:56
DataPoint Activated.	System	10 Oct 2020 19:10:27
DataPoint Inactivated.	System	10 Oct 2020 19:10:13

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
DataPoint Activated.	System	10 Oct 2020 19:10:27
DataPoint Inactivated.	System	10 Oct 2020 19:10:13
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 04:07:30

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
DataPoint Activated.	System	10 Oct 2020 19:10:27
DataPoint Inactivated.	System	10 Oct 2020 19:10:13
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 04:07:30

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	10 Oct 2020 19:10:27
User entered 'Day 21'	System	10 Oct 2020 19:10:27

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-12T16:44:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '61dcf23e-28f4-41df-ad0a-78def8ec6dfd'	System	12 Oct 2020 20:44:45
User entered 'No (N)'	System	12 Oct 2020 20:44:45

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-12T16:44:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '61dcf23e-28f4-41df-ad0a-78def8ec6dfd'	System	12 Oct 2020 20:44:45
User entered '12 Oct 2020 16:44'	System	12 Oct 2020 20:44:45

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 19:10:27

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 19:10:27

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Oct 2020 03:59:53
User entered 'Day 22'	System	12 Oct 2020 03:59:53

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-13T16:16:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0b27cba6-4fff-464b-9874-547dbc00984d'	System	13 Oct 2020 20:17:04
User entered 'No (N)'	System	13 Oct 2020 20:17:04

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-13T16:17:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0b27cba6-4fff-464b-9874-547dbc00984d'	System	13 Oct 2020 20:17:04
User entered '13 Oct 2020 16:17'	System	13 Oct 2020 20:17:04

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 03:59:53

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 03:59:53

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Oct 2020 20:44:37
User entered 'Day 23'	System	12 Oct 2020 20:44:37

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-14T12:07:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd9665bf3-159e-4a96-9da3-d81cb07e4bce'	System	14 Oct 2020 16:07:35
User entered 'No (N)'	System	14 Oct 2020 16:07:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-14T12:07:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd9665bf3-159e-4a96-9da3-d81cb07e4bce'	System	14 Oct 2020 16:07:35
User entered '14 Oct 2020 12:07'	System	14 Oct 2020 16:07:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 20:44:37

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 20:44:37

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	13 Oct 2020 20:16:59
User entered 'Day 24'	System	13 Oct 2020 20:16:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-15T15:11:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd90bce60-c87a-4f3d-8fd0-c62c0f59c793'	System	15 Oct 2020 19:11:17
User entered 'No (N)'	System	15 Oct 2020 19:11:17

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-15T15:11:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd90bce60-c87a-4f3d-8fd0-c62c0f59c793'	System	15 Oct 2020 19:11:17
User entered '15 Oct 2020 15:11'	System	15 Oct 2020 19:11:17

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:16:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:16:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	14 Oct 2020 16:07:25
User entered 'Day 25'	System	14 Oct 2020 16:07:25

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-16T12:58:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd12dc266-211d-4c6f-8371-cd0f5d703fcb'	System	16 Oct 2020 16:59:01
User entered 'No (N)'	System	16 Oct 2020 16:59:01

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-16T12:58:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd12dc266-211d-4c6f-8371-cd0f5d703fcb'	System	16 Oct 2020 16:59:01
User entered '16 Oct 2020 12:58'	System	16 Oct 2020 16:59:01

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 16:07:25

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 16:07:25

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	15 Oct 2020 19:11:10
User entered 'Day 26'	System	15 Oct 2020 19:11:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-17T16:21:34', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9cfb37e3-7c98-4d28-8c29-d54465a2ba82'	System	17 Oct 2020 20:21:41
User entered 'No (N)'	System	17 Oct 2020 20:21:41

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-17T16:21:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9cfb37e3-7c98-4d28-8c29-d54465a2ba82'	System	17 Oct 2020 20:21:41
User entered '17 Oct 2020 16:21'	System	17 Oct 2020 20:21:41

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:11:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:11:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	16 Oct 2020 16:58:54
User entered 'Day 27'	System	16 Oct 2020 16:58:54

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-18T14:23:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '170efe24-d8f0-434b-8d48-084672779454'	System	18 Oct 2020 18:23:18
User entered 'No (N)'	System	18 Oct 2020 18:23:18

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-18T14:23:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '170efe24-d8f0-434b-8d48-084672779454'	System	18 Oct 2020 18:23:18
User entered '18 Oct 2020 14:23'	System	18 Oct 2020 18:23:18

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 16:58:54

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 16:58:54

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	17 Oct 2020 20:21:36
User entered 'Day 28'	System	17 Oct 2020 20:21:36

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-20T00:00:59', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03dbb008-ecf7-459d-93fa-3a6e149f33e7'	System	20 Oct 2020 04:01:08
User entered 'No (N)'	System	20 Oct 2020 04:01:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-20T00:01:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '03dbb008-ecf7-459d-93fa-3a6e149f33e7'	System	20 Oct 2020 04:01:08
User entered '20 Oct 2020 00:01'	System	20 Oct 2020 04:01:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 20:21:36

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 20:21:36

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	18 Oct 2020 18:23:12
User entered 'Day 29'	System	18 Oct 2020 18:23:12

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-20T12:59:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a5a5c44f-d38b-499a-bf5f-efdcda11303f'	System	20 Oct 2020 16:59:52
User entered 'No (N)'	System	20 Oct 2020 16:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-20T12:59:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a5a5c44f-d38b-499a-bf5f-efdcda11303f' User entered '20 Oct 2020 12:59'	System	20 Oct 2020 16:59:52
	System	20 Oct 2020 16:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 18:23:12

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 18:23:12

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	20 Oct 2020 04:00:59
User entered 'Day 30'	System	20 Oct 2020 04:00:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-21T21:34:02', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '467245d0-ec21-4003-9f47-86cf5282c54e'	System	22 Oct 2020 01:34:09
User entered 'No (N)'	System	22 Oct 2020 01:34:09

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-21T21:34:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '467245d0-ec21-4003-9f47-86cf5282c54e'	System	22 Oct 2020 01:34:09
User entered '21 Oct 2020 21:34'	System	22 Oct 2020 01:34:09

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 04:00:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 04:00:59

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	20 Oct 2020 16:59:46
User entered 'Day 31'	System	20 Oct 2020 16:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-22T18:21:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c912a025-9096-4083-9ccd-4ce4fc6b0b4c'	System	22 Oct 2020 22:21:55
User entered 'No (N)'	System	22 Oct 2020 22:21:55

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-22T18:21:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c912a025-9096-4083-9ccd-4ce4fc6b0b4c'	System	22 Oct 2020 22:21:55
User entered '22 Oct 2020 18:21'	System	22 Oct 2020 22:21:55

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 16:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 16:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Oct 2020 01:34:04
User entered 'Day 32'	System	22 Oct 2020 01:34:04

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-23T15:52:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '28884470-c248-43f3-8080-472104411c8b'	System	23 Oct 2020 19:52:08
User entered 'No (N)'	System	23 Oct 2020 19:52:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-23T15:52:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '28884470-c248-43f3-8080-472104411c8b'	System	23 Oct 2020 19:52:08
User entered '23 Oct 2020 15:52'	System	23 Oct 2020 19:52:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 01:34:04

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 01:34:04

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	22 Oct 2020 22:21:51
User entered 'Day 33'	System	22 Oct 2020 22:21:51

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-24T21:21:33', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '831abbae-cb8e-44e4-88a2-e8079adb037d'	System	25 Oct 2020 01:21:40
User entered 'No (N)'	System	25 Oct 2020 01:21:40

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-24T21:21:37', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '831abbae-cb8e-44e4-88a2-e8079adb037d'	System	25 Oct 2020 01:21:40
User entered '24 Oct 2020 21:21'	System	25 Oct 2020 01:21:40

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 22:21:51

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 22:21:51

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	23 Oct 2020 19:52:11
User entered 'Day 34'	System	23 Oct 2020 19:52:11

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-25T16:49:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5cf4c0f-d070-4b4e-a3a2-65461cdd5bc8'	System	25 Oct 2020 20:49:19
User entered 'No (N)'	System	25 Oct 2020 20:49:19

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-25T16:49:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'c5cf4c0f-d070-4b4e-a3a2-65461cdd5bc8'	System	25 Oct 2020 20:49:19
User entered '25 Oct 2020 16:49'	System	25 Oct 2020 20:49:19

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 19:52:11

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 19:52:11

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	25 Oct 2020 01:21:35
User entered 'Day 35'	System	25 Oct 2020 01:21:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-26T15:18:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e888e01e-5ef8-4478-a6eb-c85653ce7e3a'	System	26 Oct 2020 19:18:12
User entered 'No (N)'	System	26 Oct 2020 19:18:12

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-26T15:18:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e888e01e-5ef8-4478-a6eb-c85653ce7e3a'	System	26 Oct 2020 19:18:12
User entered '26 Oct 2020 15:18'	System	26 Oct 2020 19:18:12

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 01:21:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(35)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 01:21:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	25 Oct 2020 20:49:10
User entered 'Day 36'	System	25 Oct 2020 20:49:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-27T13:14:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dc67ae3f-53de-4cb6-a270-c247a8009d80'	System	27 Oct 2020 17:15:02
User entered 'No (N)'	System	27 Oct 2020 17:15:02

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-27T13:14:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'dc67ae3f-53de-4cb6-a270-c247a8009d80'	System	27 Oct 2020 17:15:02
User entered '27 Oct 2020 13:14'	System	27 Oct 2020 17:15:02

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '27 Oct 2020 12:00'	System	25 Oct 2020 20:49:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(36)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Oct 2020 11:59'	System	25 Oct 2020 20:49:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	26 Oct 2020 19:18:07
User entered 'Day 37'	System	26 Oct 2020 19:18:07

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-28T13:14:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e968472c-3b25-45eb-ae23-8a38b81dcf62'	System	28 Oct 2020 17:14:35
User entered 'No (N)'	System	28 Oct 2020 17:14:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-28T13:14:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'e968472c-3b25-45eb-ae23-8a38b81dcf62'	System	28 Oct 2020 17:14:35
User entered '28 Oct 2020 13:14'	System	28 Oct 2020 17:14:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 19:18:07

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(37)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 19:18:07

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	27 Oct 2020 17:14:55
User entered 'Day 38'	System	27 Oct 2020 17:14:55

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-29T12:11:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '514230b8-21d9-4c51-b3f8-f1f422cbe133'	System	29 Oct 2020 16:11:38
User entered 'No (N)'	System	29 Oct 2020 16:11:38

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-29T12:11:32', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '514230b8-21d9-4c51-b3f8-f1f422cbe133'	System	29 Oct 2020 16:11:38
User entered '29 Oct 2020 12:11'	System	29 Oct 2020 16:11:38

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 17:14:55

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(38)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 17:14:55

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	28 Oct 2020 17:14:28
User entered 'Day 39'	System	28 Oct 2020 17:14:28

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-30T19:41:54', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0fdf71d3-f699-4b04-9645-0c8dd16f19a3'	System	30 Oct 2020 23:42:03
User entered 'No (N)'	System	30 Oct 2020 23:42:03

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-30T19:41:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0fdf71d3-f699-4b04-9645-0c8dd16f19a3'	System	30 Oct 2020 23:42:03
User entered '30 Oct 2020 19:41'	System	30 Oct 2020 23:42:03

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '30 Oct 2020 12:00'	System	28 Oct 2020 17:14:28

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(39)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Oct 2020 11:59'	System	28 Oct 2020 17:14:28

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	29 Oct 2020 16:11:30
User entered 'Day 40'	System	29 Oct 2020 16:11:30

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-31T12:08:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '94a4bc5e-9972-4098-b70f-fe5a4cbb4c7b'	System	31 Oct 2020 16:08:49
User entered 'No (N)'	System	31 Oct 2020 16:08:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-31T12:08:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '94a4bc5e-9972-4098-b70f-fe5a4cbb4c7b'	System	31 Oct 2020 16:08:49
User entered '31 Oct 2020 12:08'	System	31 Oct 2020 16:08:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '31 Oct 2020 12:00'	System	29 Oct 2020 16:11:30

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(40)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Nov 2020 11:59'	System	29 Oct 2020 16:11:30

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	30 Oct 2020 23:41:52
User entered 'Day 41'	System	30 Oct 2020 23:41:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-01T23:59:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9e43b897-02c3-499c-88ae-e5fd67051eb4'	System	02 Nov 2020 04:59:54
User entered 'No (N)'	System	02 Nov 2020 04:59:54

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-01T23:59:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9e43b897-02c3-499c-88ae-e5fd67051eb4'	System	02 Nov 2020 04:59:54
User entered '01 Nov 2020 23:59'	System	02 Nov 2020 04:59:54

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 23:41:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(41)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 23:41:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	31 Oct 2020 16:08:44
User entered 'Day 42'	System	31 Oct 2020 16:08:44

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-02T12:32:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ab7fad2d-e3b7-42f5-9847-aa34e73f1ea1'	System	02 Nov 2020 17:32:14
User entered 'No (N)'	System	02 Nov 2020 17:32:14

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-02T12:32:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ab7fad2d-e3b7-42f5-9847-aa34e73f1ea1'	System	02 Nov 2020 17:32:14
User entered '02 Nov 2020 12:32'	System	02 Nov 2020 17:32:14

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '02 Nov 2020 12:00'	System	31 Oct 2020 16:08:44

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(42)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Nov 2020 11:59'	System	31 Oct 2020 16:08:44

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Nov 2020 04:59:50
User entered 'Day 43'	System	02 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-03T12:14:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4e8e0ed0-4ba1-4b05-afa4-c56d19878e1f'	System	03 Nov 2020 17:14:14
User entered 'No (N)'	System	03 Nov 2020 17:14:14

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-03T12:14:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4e8e0ed0-4ba1-4b05-afa4-c56d19878e1f'	System	03 Nov 2020 17:14:14
User entered '03 Nov 2020 12:14'	System	03 Nov 2020 17:14:14

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '03 Nov 2020 12:00'	System	02 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(43)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Nov 2020 11:59'	System	02 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	02 Nov 2020 17:32:08
User entered 'Day 44'	System	02 Nov 2020 17:32:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-04T14:52:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '75e51d1a-08ea-4ea0-969d-de4801171190'	System	04 Nov 2020 19:52:56
User entered 'No (N)'	System	04 Nov 2020 19:52:56

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-04T14:52:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '75e51d1a-08ea-4ea0-969d-de4801171190'	System	04 Nov 2020 19:52:56
User entered '04 Nov 2020 14:52'	System	04 Nov 2020 19:52:56

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '04 Nov 2020 12:00'	System	02 Nov 2020 17:32:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(44)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Nov 2020 11:59'	System	02 Nov 2020 17:32:08

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	03 Nov 2020 17:14:07
User entered 'Day 45'	System	03 Nov 2020 17:14:07

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-05T14:12:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '830e7b72-df38-4b4d-9cd8-afc6b8ae28d7'	System	05 Nov 2020 19:12:14
User entered 'No (N)'	System	05 Nov 2020 19:12:14

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-05T14:12:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '830e7b72-df38-4b4d-9cd8-afc6b8ae28d7'	System	05 Nov 2020 19:12:14
User entered '05 Nov 2020 14:12'	System	05 Nov 2020 19:12:14

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '05 Nov 2020 12:00'	System	03 Nov 2020 17:14:07

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(45)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Nov 2020 11:59'	System	03 Nov 2020 17:14:07

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	04 Nov 2020 19:52:50
User entered 'Day 46'	System	04 Nov 2020 19:52:50

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-06T23:59:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d18d519-cdae-48e3-ba9a-e6e2e1f741df'	System	07 Nov 2020 04:59:54
User entered 'No (N)'	System	07 Nov 2020 04:59:54

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-06T23:59:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d18d519-cdae-48e3-ba9a-e6e2e1f741df'	System	07 Nov 2020 04:59:54
User entered '06 Nov 2020 23:59'	System	07 Nov 2020 04:59:54

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 19:52:50

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(46)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 19:52:50

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	05 Nov 2020 19:12:07
User entered 'Day 47'	System	05 Nov 2020 19:12:07

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-07T23:59:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ecda3c0c-de24-45ff-998d-9e826678db1d'	System	08 Nov 2020 04:59:48
User entered 'No (N)'	System	08 Nov 2020 04:59:48

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-07T23:59:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ecda3c0c-de24-45ff-998d-9e826678db1d'	System	08 Nov 2020 04:59:48
User entered '07 Nov 2020 23:59'	System	08 Nov 2020 04:59:48

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 19:12:07

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(47)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 19:12:07

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	07 Nov 2020 04:59:52
User entered 'Day 48'	System	07 Nov 2020 04:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-09T00:25:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4bee5ee4-2329-48b3-a9ec-804980fd59e6'	System	09 Nov 2020 05:25:26
User entered 'No (N)'	System	09 Nov 2020 05:25:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-09T00:25:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4bee5ee4-2329-48b3-a9ec-804980fd59e6'	System	09 Nov 2020 05:25:26
User entered '09 Nov 2020 00:25'	System	09 Nov 2020 05:25:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '08 Nov 2020 12:00'	System	07 Nov 2020 04:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(48)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Nov 2020 11:59'	System	07 Nov 2020 04:59:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	08 Nov 2020 04:59:46
User entered 'Day 49'	System	08 Nov 2020 04:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-09T13:13:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5fdccdcc-438c-4603-99f8-260669f5aa11'	System	09 Nov 2020 18:13:10
User entered 'No (N)'	System	09 Nov 2020 18:13:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-09T13:13:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '5fdccdcc-438c-4603-99f8-260669f5aa11' User entered '09 Nov 2020 13:13'	System	09 Nov 2020 18:13:10
	System	09 Nov 2020 18:13:10

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '09 Nov 2020 12:00'	System	08 Nov 2020 04:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(49)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Nov 2020 11:59'	System	08 Nov 2020 04:59:46

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Nov 2020 05:25:21
User entered 'Day 50'	System	09 Nov 2020 05:25:21

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-10T23:59:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ed99b198-f075-45bd-951d-a92200a5d759'	System	11 Nov 2020 04:59:50
User entered 'No (N)'	System	11 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-10T23:59:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'ed99b198-f075-45bd-951d-a92200a5d759'	System	11 Nov 2020 04:59:50
User entered '10 Nov 2020 23:59'	System	11 Nov 2020 04:59:50

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '10 Nov 2020 12:00'	System	09 Nov 2020 05:25:21

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(50)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Nov 2020 11:59'	System	09 Nov 2020 05:25:21

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	09 Nov 2020 18:13:05
User entered 'Day 51'	System	09 Nov 2020 18:13:05

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-12T00:31:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '59bffa-f109-4dac-b21a-3b329cd53cfa'	System	12 Nov 2020 05:31:29
User entered 'No (N)'	System	12 Nov 2020 05:31:29

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-12T00:31:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '59bffa-f109-4dac-b21a-3b329cd53cfa'	System	12 Nov 2020 05:31:29
User entered '12 Nov 2020 00:31'	System	12 Nov 2020 05:31:29

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '11 Nov 2020 12:00'	System	09 Nov 2020 18:13:05

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(51)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Nov 2020 11:59'	System	09 Nov 2020 18:13:05

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	11 Nov 2020 04:59:49
User entered 'Day 52'	System	11 Nov 2020 04:59:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-12T12:49:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '98a51c83-cd4f-4676-add9-559983aa9c6d'	System	12 Nov 2020 17:49:27
User entered 'No (N)'	System	12 Nov 2020 17:49:27

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-12T12:49:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '98a51c83-cd4f-4676-add9-559983aa9c6d' User entered '12 Nov 2020 12:49'	System	12 Nov 2020 17:49:27
	System	12 Nov 2020 17:49:27

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 04:59:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(52)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 04:59:49

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Nov 2020 05:31:24
User entered 'Day 53'	System	12 Nov 2020 05:31:24

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-13T12:00:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f33ec99b-8b10-46ce-8b8e-c02913c44ac7'	System	13 Nov 2020 17:01:42
User entered 'No (N)'	System	13 Nov 2020 17:01:42

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-13T12:00:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f33ec99b-8b10-46ce-8b8e-c02913c44ac7'	System	13 Nov 2020 17:01:42
User entered '13 Nov 2020 12:00'	System	13 Nov 2020 17:01:42

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 05:31:24

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(53)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 05:31:24

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	12 Nov 2020 17:49:26
User entered 'Day 54'	System	12 Nov 2020 17:49:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-14T18:14:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'afbe5706-f547-43c7-a0d1-a3cf35c5b367'	System	14 Nov 2020 23:14:53
User entered 'No (N)'	System	14 Nov 2020 23:14:53

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-14T18:14:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'afbe5706-f547-43c7-a0d1-a3cf35c5b367'	System	14 Nov 2020 23:14:53
User entered '14 Nov 2020 18:14'	System	14 Nov 2020 23:14:53

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 17:49:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(54)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 17:49:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	13 Nov 2020 17:01:32
User entered 'Day 55'	System	13 Nov 2020 17:01:32

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-15T17:05:28', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '406df2f3-7b05-44a7-bb36-d443f554b6f8'	System	15 Nov 2020 22:05:35
User entered 'No (N)'	System	15 Nov 2020 22:05:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-15T17:05:30', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '406df2f3-7b05-44a7-bb36-d443f554b6f8'	System	15 Nov 2020 22:05:35
User entered '15 Nov 2020 17:05'	System	15 Nov 2020 22:05:35

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '15 Nov 2020 12:00'	System	13 Nov 2020 17:01:32

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(55)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Nov 2020 11:59'	System	13 Nov 2020 17:01:32

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	14 Nov 2020 23:14:48
User entered 'Day 56'	System	14 Nov 2020 23:14:48

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-16T17:49:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8b100e17-8f1e-4b2e-89e1-ade2fd5861b0'	System	16 Nov 2020 22:49:19
User entered 'Yes (Y)'	System	16 Nov 2020 22:49:19

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-16T17:49:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '8b100e17-8f1e-4b2e-89e1-ade2fd5861b0'	System	16 Nov 2020 22:49:19
User entered '16 Nov 2020 17:49'	System	16 Nov 2020 22:49:19

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '16 Nov 2020 12:00'	System	14 Nov 2020 23:14:48

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(56)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Nov 2020 11:59'	System	14 Nov 2020 23:14:48

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	15 Nov 2020 22:05:29
User entered 'Day 57'	System	15 Nov 2020 22:05:29

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-17T12:00:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '070d3f63-b502-4feb-9498-64ce868d9f8c'	System	17 Nov 2020 17:00:43
User entered 'No (N)'	System	17 Nov 2020 17:00:43

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-17T12:00:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '070d3f63-b502-4feb-9498-64ce868d9f8c'	System	17 Nov 2020 17:00:43
User entered '17 Nov 2020 12:00'	System	17 Nov 2020 17:00:43

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '17 Nov 2020 12:00'	System	15 Nov 2020 22:05:29

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(57)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Nov 2020 11:59'	System	15 Nov 2020 22:05:29

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	16 Nov 2020 17:12:26
User entered 'Day 58'	System	16 Nov 2020 17:12:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:31:23', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'afcecd62-83a9-4978-a5c9-37ef34f4a69a'	System	18 Nov 2020 17:31:31
User entered 'No (N)'	System	18 Nov 2020 17:31:31

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:31:25', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'afcecd62-83a9-4978-a5c9-37ef34f4a69a'	System	18 Nov 2020 17:31:31
User entered '18 Nov 2020 12:31'	System	18 Nov 2020 17:31:31

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 17:12:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(58)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 17:12:26

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	17 Nov 2020 17:00:32
User entered 'Day 59'	System	17 Nov 2020 17:00:32

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-19T12:05:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'df13e4b4-b8af-492c-b1e3-08929b06707f'	System	19 Nov 2020 17:05:42
User entered 'No (N)'	System	19 Nov 2020 17:05:42

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-19T12:05:32', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'df13e4b4-b8af-492c-b1e3-08929b06707f'	System	19 Nov 2020 17:05:42
User entered '19 Nov 2020 12:05'	System	19 Nov 2020 17:05:42

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '19 Nov 2020 12:00'	System	17 Nov 2020 17:00:32

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(59)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Nov 2020 11:59'	System	17 Nov 2020 17:00:32

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	18 Nov 2020 17:31:21
User entered 'Day 60'	System	18 Nov 2020 17:31:21

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-20T21:03:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7ccd6a16-815c-4fd7-9e1e-f7f47a342a48'	System	21 Nov 2020 02:03:52
User entered 'No (N)'	System	21 Nov 2020 02:03:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-20T21:03:49', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7ccd6a16-815c-4fd7-9e1e-f7f47a342a48'	System	21 Nov 2020 02:03:52
User entered '20 Nov 2020 21:03'	System	21 Nov 2020 02:03:52

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 17:31:21

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(60)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 17:31:21

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	19 Nov 2020 17:05:28
User entered 'Day 61'	System	19 Nov 2020 17:05:28

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 17:05:28

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(61)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 17:05:28

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Nov 2020 02:03:47
User entered 'Day 62'	System	21 Nov 2020 02:03:47

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 10 Jun 2021 09:24:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 10 Jun 2021 09:24:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '22 Nov 2020 12:00'	System	21 Nov 2020 02:03:47

US3672255

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(62)

Generated On: 10 Jun 2021 09:24:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
User entered '23 Nov 2020 11:59'	System	21 Nov 2020 02:03:47

US3672255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 20:38:17

US3672255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '29 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 20:38:17

US3672255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 20:38:17

US3672255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 20:38:17

US3672255

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 20:38:22

US3672255

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	30 Sep 2020 20:38:22

US3672255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:04:03

US3672255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:04:03

US3672255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:04:03

US3672255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:04:03

US3672255

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:04:06

US3672255

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	13 Oct 2020 19:04:06

US3672255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:04:30

US3672255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:04:30

US3672255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:04:30

US3672255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:04:30

US3672255

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:04:32

US3672255

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	13 Oct 2020 19:04:32

US3672255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:56:44

US3672255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '19 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 19:56:44

US3672255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Oct 2020 19:56:44

US3672255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'VISIT3'	System	21 Oct 2020 19:56:44

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '19 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '15:22'	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '19 Oct 2020 15:22'	System	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '99.2' F	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '94'	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'bpm'	System	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '17'	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'breaths/min'	System	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '109'	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '75'	(b) (4), (b) (6)	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'mmHg'	System	21 Oct 2020 19:57:12

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24

US3672255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24

US3672255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 19:57:21

US3672255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:57:21

US3672255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:57:34

US3672255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:57:34

US3672255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered '15:33'	(b) (4), (b) (6)	21 Oct 2020 19:57:34

US3672255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered '19 Oct 2020 15:33'	System	21 Oct 2020 19:57:34

US3672255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:06:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:57:38

US3672255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	21 Oct 2020 19:57:38

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 64'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-21T00:36:32', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '895300c7-5217-4d81-b5cc-9f55d637896c'	System	21 Oct 2020 04:36:54
User entered 'Yes (Y)'	System	21 Oct 2020 04:36:54

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-21T00:36:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '895300c7-5217-4d81-b5cc-9f55d637896c'	System	21 Oct 2020 04:36:54
User entered 'No (N)'	System	21 Oct 2020 04:36:54

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-21T00:36:39', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '895300c7-5217-4d81-b5cc-9f55d637896c'	System	21 Oct 2020 04:36:54
User entered 'No (N)'	System	21 Oct 2020 04:36:54

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-21T00:36:44', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '895300c7-5217-4d81-b5cc-9f55d637896c'	System	21 Oct 2020 04:36:54
User entered 'No (N)'	System	21 Oct 2020 04:36:54

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-21T00:36:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '895300c7-5217-4d81-b5cc-9f55d637896c' User entered '21 Oct 2020 00:36:48'	System	21 Oct 2020 04:36:54
	System	21 Oct 2020 04:36:54

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 71'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-28T00:01:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2ecce063-1afb-40f1-b720-909aee9d33b0'	System	28 Oct 2020 04:01:40
User entered 'No (N)'	System	28 Oct 2020 04:01:40

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-28T00:01:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2ecce063-1afb-40f1-b720-909aee9d33b0'	System	28 Oct 2020 04:01:40
User entered 'No (N)'	System	28 Oct 2020 04:01:40

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-10-28T00:01:35', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '2ecce063-1afb-40f1-b720-909aee9d33b0'	System	28 Oct 2020 04:01:40
User entered '28 Oct 2020 00:01:35'	System	28 Oct 2020 04:01:40

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 78'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-04T14:52:58', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'af589953-7de7-4073-9904-16205fc143a6'	System	04 Nov 2020 19:53:09
User entered 'No (N)'	System	04 Nov 2020 19:53:09

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-04T14:53:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'af589953-7de7-4073-9904-16205fc143a6'	System	04 Nov 2020 19:53:09
User entered 'No (N)'	System	04 Nov 2020 19:53:09

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-04T14:53:04', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'af589953-7de7-4073-9904-16205fc143a6'	System	04 Nov 2020 19:53:09
User entered '04 Nov 2020 14:53:04'	System	04 Nov 2020 19:53:09

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered 'Day 92'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:31:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '38dd662b-e8f0-4181-94ee-83fd0878785a'	System	18 Nov 2020 17:32:26
User entered 'Yes (Y)'	System	18 Nov 2020 17:32:26

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:31:55', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '38dd662b-e8f0-4181-94ee-83fd0878785a'	System	18 Nov 2020 17:32:26
User entered 'No (N)'	System	18 Nov 2020 17:32:26

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:32:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '38dd662b-e8f0-4181-94ee-83fd0878785a'	System	18 Nov 2020 17:32:26
User entered 'No (N)'	System	18 Nov 2020 17:32:26

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:32:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '38dd662b-e8f0-4181-94ee-83fd0878785a'	System	18 Nov 2020 17:32:26
User entered 'Yes (Y)'	System	18 Nov 2020 17:32:26

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Please 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)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:32:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '38dd662b-e8f0-4181-94ee-83fd0878785a'	System	18 Nov 2020 17:32:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 17:32:26

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-18T12:32:15', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '38dd662b-e8f0-4181-94ee-83fd0878785a'	System	18 Nov 2020 17:32:26
User entered '18 Nov 2020 12:32:15'	System	18 Nov 2020 17:32:26

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 19:26:56

US3672255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:33:13
Data entry locked.	System	21 Aug 2020 19:26:56
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 19:26:56

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-11-23T16:04:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b82b9c8e-eed6-440d-bcad-1554084a9f23'	System	23 Nov 2020 21:04:55
User entered 'Yes (Y)'	System	23 Nov 2020 21:04:55

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2020-11-23T16:04:22', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b82b9c8e-eed6-440d-bcad-1554084a9f23'	System	23 Nov 2020 21:04:55
User entered 'No (N)'	System	23 Nov 2020 21:04:55

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-11-23T16:04:27', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b82b9c8e-eed6-440d-bcad-1554084a9f23'	System	23 Nov 2020 21:04:55
User entered 'No (N)'	System	23 Nov 2020 21:04:55

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-11-23T16:04:32', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b82b9c8e-eed6-440d-bcad-1554084a9f23'	System	23 Nov 2020 21:04:55
User entered 'Yes (Y)'	System	23 Nov 2020 21:04:55

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Please 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 (37e6fe95438046db)', Time: '2020-11-23T16:04:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b82b9c8e-eed6-440d-bcad-1554084a9f23'	System	23 Nov 2020 21:04:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 21:04:55

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-23T16:04:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'b82b9c8e-eed6-440d-bcad-1554084a9f23'	System	23 Nov 2020 21:04:55
User entered '23 Nov 2020 16:04:46'	System	23 Nov 2020 21:04:55

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-11-29T00:10:46', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1cbdc7b8-34f9-45df-94a8-a20bea4c83ed'	System	29 Nov 2020 05:11:19
User entered 'Yes (Y)'	System	29 Nov 2020 05:11:19

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2020-11-29T00:10:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1cbdc7b8-34f9-45df-94a8-a20bea4c83ed'	System	29 Nov 2020 05:11:19
User entered 'No (N)'	System	29 Nov 2020 05:11:19

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-11-29T00:10:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1cbdc7b8-34f9-45df-94a8-a20bea4c83ed'	System	29 Nov 2020 05:11:19
User entered 'No (N)'	System	29 Nov 2020 05:11:19

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-11-29T00:11:02', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1cbdc7b8-34f9-45df-94a8-a20bea4c83ed'	System	29 Nov 2020 05:11:19
User entered 'Yes (Y)'	System	29 Nov 2020 05:11:19

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Please 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 (37e6fe95438046db)', Time: '2020-11-29T00:11:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1cbdc7b8-34f9-45df-94a8-a20bea4c83ed'	System	29 Nov 2020 05:11:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Nov 2020 05:11:19

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-11-29T00:11:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1cbdc7b8-34f9-45df-94a8-a20bea4c83ed' User entered '29 Nov 2020 00:11:08'	System	29 Nov 2020 05:11:19
	System	29 Nov 2020 05:11:19

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-12-06T00:01:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '87cd6b72-9127-49fc-a8a8-74e47a9b498c'	System	06 Dec 2020 05:01:47
User entered 'No (N)'	System	06 Dec 2020 05:01:47

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2020-12-06T00:01:34', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '87cd6b72-9127-49fc-a8a8-74e47a9b498c'	System	06 Dec 2020 05:01:47
User entered 'No (N)'	System	06 Dec 2020 05:01:47

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-06T00:01:36', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '87cd6b72-9127-49fc-a8a8-74e47a9b498c'	System	06 Dec 2020 05:01:47
User entered '06 Dec 2020 00:01:36'	System	06 Dec 2020 05:01:47

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-12-13T02:37:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0787db55-3573-49a9-a231-f20802a3d5f3'	System	13 Dec 2020 07:37:36
User entered 'No (N)'	System	13 Dec 2020 07:37:36

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2020-12-13T02:37:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0787db55-3573-49a9-a231-f20802a3d5f3'	System	13 Dec 2020 07:37:36
User entered 'No (N)'	System	13 Dec 2020 07:37:36

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-13T02:37:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0787db55-3573-49a9-a231-f20802a3d5f3'	System	13 Dec 2020 07:37:36
User entered '13 Dec 2020 02:37:24'	System	13 Dec 2020 07:37:36

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-12-20T00:51:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'cd3860cc-53d1-40dc-9b29-29b8473880c7'	System	20 Dec 2020 05:51:38
User entered 'No (N)'	System	20 Dec 2020 05:51:38

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2020-12-20T00:51:29', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'cd3860cc-53d1-40dc-9b29-29b8473880c7'	System	20 Dec 2020 05:51:38
User entered 'No (N)'	System	20 Dec 2020 05:51:38

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-20T00:51:31', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'cd3860cc-53d1-40dc-9b29-29b8473880c7'	System	20 Dec 2020 05:51:38
User entered '20 Dec 2020 00:51:31'	System	20 Dec 2020 05:51:38

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-12-27T00:36:14', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered 'Yes (Y)'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2020-12-27T00:36:21', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered 'No (N)'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-12-27T00:36:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered 'Yes (Y)'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '0'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '0'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '0'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '1'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '0'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '0'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered '0'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Please 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 (37e6fe95438046db)', Time: '2020-12-27T00:36:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2020-12-27T00:36:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e'	System	27 Dec 2020 05:37:06
User entered 'No (N)'	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2020-12-27T00:36:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd11c6bab-6bfc-415a-bc4f-cef2be932b1e' User entered '27 Dec 2020 00:36:56'	System	27 Dec 2020 05:37:06
	System	27 Dec 2020 05:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-01-03T19:39:47', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7964c831-bbe7-464b-a1cb-5ff8e0ecad87'	System	04 Jan 2021 00:39:54
User entered 'No (N)'	System	04 Jan 2021 00:39:54

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-01-03T19:39:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7964c831-bbe7-464b-a1cb-5ff8e0ecad87'	System	04 Jan 2021 00:39:54
User entered 'No (N)'	System	04 Jan 2021 00:39:54

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-01-03T19:39:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7964c831-bbe7-464b-a1cb-5ff8e0ecad87'	System	04 Jan 2021 00:39:54
User entered '03 Jan 2021 19:39:52'	System	04 Jan 2021 00:39:54

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-01-10T00:03:03', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d335afe-461c-43bf-ae01-5aa0eaeca7b7'	System	10 Jan 2021 05:04:14
User entered 'No (N)'	System	10 Jan 2021 05:04:14

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-01-10T00:03:11', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d335afe-461c-43bf-ae01-5aa0eaeca7b7'	System	10 Jan 2021 05:04:14
User entered 'No (N)'	System	10 Jan 2021 05:04:14

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-01-10T00:03:13', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0d335afe-461c-43bf-ae01-5aa0eaeca7b7'	System	10 Jan 2021 05:04:14
User entered '10 Jan 2021 00:03:13'	System	10 Jan 2021 05:04:14

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-01-17T00:04:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ff3f9f4-cedb-4ff4-9bc9-c1b2d11f9686'	System	17 Jan 2021 05:05:14
User entered 'No (N)'	System	17 Jan 2021 05:05:14

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-01-17T00:04:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ff3f9f4-cedb-4ff4-9bc9-c1b2d11f9686'	System	17 Jan 2021 05:05:14
User entered 'Yes (Y)'	System	17 Jan 2021 05:05:14

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Please 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 (37e6fe95438046db)', Time: '2021-01-17T00:04:56', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ff3f9f4-cedb-4ff4-9bc9-c1b2d11f9686'	System	17 Jan 2021 05:05:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Jan 2021 05:05:14

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-01-17T00:05:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ff3f9f4-cedb-4ff4-9bc9-c1b2d11f9686'	System	17 Jan 2021 05:05:14
User entered '17 Jan 2021 00:05:01'	System	17 Jan 2021 05:05:14

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-01-25T12:34:53', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd420f830-999e-454a-98c6-a1afc2730ebd'	System	25 Jan 2021 17:35:18
User entered 'No (N)'	System	25 Jan 2021 17:35:18

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-01-25T12:35:01', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd420f830-999e-454a-98c6-a1afc2730ebd'	System	25 Jan 2021 17:35:18
User entered 'Yes (Y)'	System	25 Jan 2021 17:35:18

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Please 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 (37e6fe95438046db)', Time: '2021-01-25T12:35:05', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd420f830-999e-454a-98c6-a1afc2730ebd'	System	25 Jan 2021 17:35:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 17:35:18

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-01-25T12:35:07', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd420f830-999e-454a-98c6-a1afc2730ebd' User entered '25 Jan 2021 12:35:07'	System	25 Jan 2021 17:35:18
	System	25 Jan 2021 17:35:18

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-02-09T22:51:51', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '88772470-dff2-4b88-ae5a-24ce135998ce'	System	10 Feb 2021 03:53:19
User entered 'No (N)'	System	10 Feb 2021 03:53:19

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-02-09T22:51:55', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '88772470-dff2-4b88-ae5a-24ce135998ce'	System	10 Feb 2021 03:53:19
User entered 'No (N)'	System	10 Feb 2021 03:53:19

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-02-09T22:51:57', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '88772470-dff2-4b88-ae5a-24ce135998ce' User entered '09 Feb 2021 22:51:57'	System	10 Feb 2021 03:53:19

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-02-14T19:05:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1994f26f-d03d-4571-998e-18f50289813b'	System	15 Feb 2021 00:09:17
User entered 'No (N)'	System	15 Feb 2021 00:09:17

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-02-14T19:05:43', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1994f26f-d03d-4571-998e-18f50289813b'	System	15 Feb 2021 00:09:17
User entered 'No (N)'	System	15 Feb 2021 00:09:17

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-02-14T19:05:45', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '1994f26f-d03d-4571-998e-18f50289813b' User entered '14 Feb 2021 19:05:45'	System	15 Feb 2021 00:09:17

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-02-21T07:47:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f635a0ee-ae68-47d3-843c-cc7a8a9ad808'	System	21 Feb 2021 12:47:15
User entered 'No (N)'	System	21 Feb 2021 12:47:15

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-02-21T07:47:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f635a0ee-ae68-47d3-843c-cc7a8a9ad808'	System	21 Feb 2021 12:47:15
User entered 'No (N)'	System	21 Feb 2021 12:47:15

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-02-21T07:47:12', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f635a0ee-ae68-47d3-843c-cc7a8a9ad808'	System	21 Feb 2021 12:47:15
User entered '21 Feb 2021 07:47:12'	System	21 Feb 2021 12:47:15

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-03-01T01:06:06', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9fff125b-d268-4613-858f-b665adb922d7'	System	01 Mar 2021 06:06:15
User entered 'No (N)'	System	01 Mar 2021 06:06:15

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-03-01T01:06:08', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9fff125b-d268-4613-858f-b665adb922d7'	System	01 Mar 2021 06:06:15
User entered 'No (N)'	System	01 Mar 2021 06:06:15

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-03-01T01:06:10', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9fff125b-d268-4613-858f-b665adb922d7'	System	01 Mar 2021 06:06:15
User entered '01 Mar 2021 01:06:10'	System	01 Mar 2021 06:06:15

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-03-07T00:23:37', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd7c0bfd0-366a-442a-af9b-8d4b677bc4b0'	System	07 Mar 2021 05:23:43
User entered 'No (N)'	System	07 Mar 2021 05:23:43

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-03-07T00:23:40', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd7c0bfd0-366a-442a-af9b-8d4b677bc4b0'	System	07 Mar 2021 05:23:43
User entered 'No (N)'	System	07 Mar 2021 05:23:43

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-03-07T00:23:42', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd7c0bfd0-366a-442a-af9b-8d4b677bc4b0'	System	07 Mar 2021 05:23:43
User entered '07 Mar 2021 00:23:42'	System	07 Mar 2021 05:23:43

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-03-14T10:12:20', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0dc7d736-0760-420d-a87b-0323fae77203'	System	14 Mar 2021 14:12:29
User entered 'No (N)'	System	14 Mar 2021 14:12:29

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-03-14T10:12:24', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0dc7d736-0760-420d-a87b-0323fae77203'	System	14 Mar 2021 14:12:29
User entered 'No (N)'	System	14 Mar 2021 14:12:29

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-03-14T10:12:26', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '0dc7d736-0760-420d-a87b-0323fae77203'	System	14 Mar 2021 14:12:29
User entered '14 Mar 2021 10:12:26'	System	14 Mar 2021 14:12:29

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-03-21T00:36:48', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f461a1b0-947e-4575-b6aa-9ac483b4d521'	System	21 Mar 2021 04:36:56
User entered 'No (N)'	System	21 Mar 2021 04:36:56

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-03-21T00:36:50', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f461a1b0-947e-4575-b6aa-9ac483b4d521'	System	21 Mar 2021 04:36:56
User entered 'No (N)'	System	21 Mar 2021 04:36:56

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-03-21T00:36:52', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'f461a1b0-947e-4575-b6aa-9ac483b4d521'	System	21 Mar 2021 04:36:56
User entered '21 Mar 2021 00:36:52'	System	21 Mar 2021 04:36:56

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-03-28T17:40:42-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ce05dfc-937f-4c7f-978e-daf94641f52e' User entered 'Yes (Y)'	System	28 Mar 2021 21:41:20
	System	28 Mar 2021 21:41:20

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-03-28T17:40:46-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ce05dfc-937f-4c7f-978e-daf94641f52e' User entered 'No (N)'	System	28 Mar 2021 21:41:20

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-03-28T17:40:49-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ce05dfc-937f-4c7f-978e-daf94641f52e' User entered 'No (N)'	System	28 Mar 2021 21:41:20
	System	28 Mar 2021 21:41:20

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-03-28T17:41:02-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ce05dfc-937f-4c7f-978e-daf94641f52e' User entered 'Yes (Y)'	System	28 Mar 2021 21:41:20
	System	28 Mar 2021 21:41:20

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Please 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 (37e6fe95438046db)', Time: '2021-03-28T17:41:07-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ce05dfc-937f-4c7f-978e-daf94641f52e'	System	28 Mar 2021 21:41:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Mar 2021 21:41:20

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-03-28T17:41:10-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '9ce05dfc-937f-4c7f-978e-daf94641f52e' User entered '28 Mar 2021 17:41:10'	System	28 Mar 2021 21:41:20
	System	28 Mar 2021 21:41:20

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-04-06T22:36:35-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4e297ea5-1556-45a1-82c5-1a9d470b6ec2' User entered 'No (N)'	System	07 Apr 2021 02:37:06
	System	07 Apr 2021 02:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-04-06T22:36:37-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4e297ea5-1556-45a1-82c5-1a9d470b6ec2'	System	07 Apr 2021 02:37:06
User entered 'No (N)'	System	07 Apr 2021 02:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-04-06T22:36:39-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '4e297ea5-1556-45a1-82c5-1a9d470b6ec2'	System	07 Apr 2021 02:37:06
User entered '06 Apr 2021 22:36:39'	System	07 Apr 2021 02:37:06

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-04-12T16:01:47-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a3a6d3f2-522d-4667-8b5b-e9abff517042'	System	12 Apr 2021 20:01:56
User entered 'No (N)'	System	12 Apr 2021 20:01:56

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-04-12T16:01:50-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a3a6d3f2-522d-4667-8b5b-e9abff517042'	System	12 Apr 2021 20:01:56
User entered 'No (N)'	System	12 Apr 2021 20:01:56

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-04-12T16:01:52-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'a3a6d3f2-522d-4667-8b5b-e9abff517042'	System	12 Apr 2021 20:01:56
User entered '12 Apr 2021 16:01:52'	System	12 Apr 2021 20:01:56

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-04-18T05:57:43-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7fdbd76c-1e2c-4ecd-a8ed-34c3b5fbcc87'	System	18 Apr 2021 09:57:52
User entered 'No (N)'	System	18 Apr 2021 09:57:52

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-04-18T05:57:45-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7fdbd76c-1e2c-4ecd-a8ed-34c3b5fbcc87'	System	18 Apr 2021 09:57:52
User entered 'No (N)'	System	18 Apr 2021 09:57:52

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-04-18T05:57:46-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '7fdbd76c-1e2c-4ecd-a8ed-34c3b5fbcc87'	System	18 Apr 2021 09:57:52
User entered '18 Apr 2021 05:57:46'	System	18 Apr 2021 09:57:52

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-04-25T00:30:01-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd532f925-6e50-4f2f-8aba-edf162765b83'	System	25 Apr 2021 04:30:12
User entered 'No (N)'	System	25 Apr 2021 04:30:12

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-04-25T00:30:05-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd532f925-6e50-4f2f-8aba-edf162765b83'	System	25 Apr 2021 04:30:12
User entered 'No (N)'	System	25 Apr 2021 04:30:12

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-04-25T00:30:07-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: 'd532f925-6e50-4f2f-8aba-edf162765b83'	System	25 Apr 2021 04:30:12
User entered '25 Apr 2021 00:30:07'	System	25 Apr 2021 04:30:12

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[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 (37e6fe95438046db)', Time: '2021-05-02T09:07:08-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3fe6e7e6-1bd1-4c5c-b9d8-82671d07d93f'	System	02 May 2021 13:07:16
User entered 'No (N)'	System	02 May 2021 13:07:16

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

Have you been exposed to someone with 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 (37e6fe95438046db)', Time: '2021-05-02T09:07:10-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3fe6e7e6-1bd1-4c5c-b9d8-82671d07d93f'	System	02 May 2021 13:07:16
User entered 'No (N)'	System	02 May 2021 13:07:16

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-05-02T09:07:12-04:00', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '3fe6e7e6-1bd1-4c5c-b9d8-82671d07d93f'	System	02 May 2021 13:07:16
User entered '02 May 2021 09:07:12'	System	02 May 2021 13:07:16

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:52:35

US3672255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:52:35
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:52:35

US3672255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:24:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:25:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-03-01T01:06:15', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '80fb5027-3d00-41ab-ba60-cc288663d155'	System	01 Mar 2021 06:06:21
User entered 'No (N)'	System	01 Mar 2021 06:06:21

US3672255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:24:23

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:25:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37e6fe95438046db)', Time: '2021-03-01T01:06:17', User OID: 'PatientReportedOutcome (US3672255)', ODM File OID: '80fb5027-3d00-41ab-ba60-cc288663d155'	System	01 Mar 2021 06:06:21
User entered '01 Mar 2021 01:06:17'	System	01 Mar 2021 06:06:21

US3672255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Nov 2020 21:38:04

US3672255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:38:04

US3672255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:38:04

US3672255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:38:04

US3672255

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:38:10

US3672255

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:57:24
User entered 'I'	System	22 Nov 2020 21:38:10

US3672255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 16:15:15

US3672255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 16:15:15

US3672255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 16:15:15

US3672255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 16:15:15

US3672255

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 16:15:20

US3672255

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User entered 'I'	System	11 Dec 2020 16:15:20

US3672255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Jan 2021 19:51:03

US3672255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:51:03

US3672255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:51:03

US3672255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:51:03

US3672255

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:51:06

US3672255

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User entered 'I'	System	18 Jan 2021 19:51:06

US3672255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:38:48

US3672255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:48

US3672255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:48

US3672255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:48

US3672255

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:38:55

US3672255

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:13:47
User entered 'I'	System	16 Feb 2021 21:38:55

US3672255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:05:20

US3672255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:05:20

US3672255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:05:20

US3672255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	22 Apr 2021 21:05:20

US3672255

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:05:36

US3672255

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 21:05:36

US3672255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:07:05

US3672255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:54
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:07:05

US3672255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:07:05

US3672255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:07:05

US3672255

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 21:07:20

US3672255

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 21:07:20

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:24:23

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '28 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:36:57

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:24:23

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '14:00'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:36:57

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:24:23

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:06
User entered '28 Dec 2020 14:00'	System	28 Dec 2020 19:36:57

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:24:23

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:36:57

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:24:23

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:06
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:36:57

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Day 1 (Day 1)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '24 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 - 4. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 11:35:23
Query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 - 4. If not collected, please consider recording as Not Done.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 20:29:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 20:29:09
User opened query 'Per CDM: It appears that O2 saturation and temperature were not provided for days 1 - 4. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 22:30:27
User entered empty.	Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User entered '%'	System	24 Jan 2021 20:29:09
User entered empty.	System	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 20:29:09
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:24:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	Patty Howenstine (b) (4)	28 Dec 2020 19:37:58

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Day 2 (Day 2)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '25 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 20:29:09
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User entered '%'	System	24 Jan 2021 20:29:09
User entered empty.	System	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 20:29:09
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:24:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:38:50

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Day 3 (Day 3)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '26 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 20:29:09
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User entered '%'	System	24 Jan 2021 20:29:09
User entered empty.	System	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 20:29:09
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:24:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:39:29

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Day 4 (Day 4)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '27 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 20:29:09
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User entered '%'	System	24 Jan 2021 20:29:09
User entered empty.	System	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Jan 2021 20:29:09
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:24:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:05

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Day 5 (Day 5)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '28 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '99'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User entered '%'	System	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '97.2' F	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:24:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:40:46

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:34:26
User entered '96'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User entered '%'	System	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '99.5' F	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:24:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)'	(b) (4), (b) (6)	31 Dec 2020 18:51:11

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '96' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:34:26
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User entered '%'	System	31 Dec 2020 19:34:26
User entered empty.	System	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '99.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:34:55
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:24:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 18:51:31

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '99'	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User entered '%'	System	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '99' F reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:34:55
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:36:54
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:24:23

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:39:40
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:34:26

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '28 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:41:27

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	28 Dec 2020 19:41:27

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per CDM: Response noted. Please update the result when data is available and keep the query open until result is updated.' (Site from DM).	(b) (4)	
Query 'Per CDM: Response noted. Please update the result when data is available and keep the query open until result is updated.' answered with 'ok' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 05:39:03
Query 'Per CDM: Response noted. Please update the result when data is available and keep the query open until result is updated.' answered with 'ok' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 19:40:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:40:06
User opened query 'Per CDM: Response noted. Please update the result when data is available and keep the query open until result is updated.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 04:50:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 04:50:36
Query 'Data is required. Please complete.' answered with 'waiting on results' (Site from System).	Patty Howenstine (b) (4)	28 Dec 2020 19:41:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	28 Dec 2020 19:41:27
	Patty Howenstine (b) (4)	28 Dec 2020 19:41:27
	(b) (4)	

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '28 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:41:27

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:41:27

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:41:27

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:41:27

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:41:27

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:41:27

US3672255

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:24:23

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:37:32
User entered '0'	System	31 Dec 2020 19:40:06

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:24:23

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User accepted default value 'Day 3 (Day 3)'	Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:24:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	24 Feb 2021 16:39:45
User entered 'NA (COVID-19 Negative) (NA)'	Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:24:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Patty Howenstine (b) (4)	24 Feb 2021 16:39:45
User entered empty.	(b) (4)	
	Patty Howenstine (b) (4)	05 Feb 2021 17:48:41
	(b) (4)	

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:24:23

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User accepted default value 'Day 5 (Day 5)'	Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:24:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:24:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:24:23

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User accepted default value 'Day 7 (Day 7)'	Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:24:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:24:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:24:23

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User accepted default value 'Day 9 (Day 9)'	Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:24:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:24:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:24:23

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User accepted default value 'Day 14 (Day 14)'	Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:24:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:24:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:24:23

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User accepted default value 'Day 21 (Day 21)'	Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:24:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:24:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:24:23

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User accepted default value 'Day 28 (Day 28)'	Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:24:23

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:24:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 17:48:41

US3672255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:17
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:41:50

US3672255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:17
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 30DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please review the preclaus data and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 30DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please review the preclaus data and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' answered with 'Saliva Day 3 results in PPD - Accession Number: 1F60ATI ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:50:50
	Patty Howenstine (b) (4)	24 Feb 2021 16:39:31
User opened query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 30DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please review the preclaus data and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:05:13

US3672255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:04:21
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'Covid negative, no samples available.' (Site from DM).	Patty Howenstine (b) (4)	05 Feb 2021 17:49:02
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 05:54:25
User entered '28 Dec 2020'	Patty Howenstine (b) (4)	28 Dec 2020 19:41:50

US3672255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:17
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Clinic (Clinic)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:41:50

US3672255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:17
User entered 'SICKD1'	System	28 Dec 2020 19:41:50

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '28 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '14:05'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User entered '28 Dec 2020 14:05'	System	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '173.60' cm	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26
DataPoint set to visible.	(b) (4) System	28 Dec 2020 19:41:50

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
Query 'Per CDM: Please confirm if Height and Weight values are correct. Patient may have Severe Obesity. If so, please update Medical History. Thank you' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:06:13
User opened query 'Per CDM: Please confirm if Height and Weight values are correct. Patient may have Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:05:28
User entered '149.3' kg	Patty Howenstine (b) (4)	28 Dec 2020 19:42:26
DataPoint set to visible.	(b) (4) System	28 Dec 2020 19:41:50

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '97.2' F	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Other (Other)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'forehead'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '96'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User entered 'bpm'	System	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '16'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User entered 'breaths/min'	System	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '137'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User entered 'mmHg'	System	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '95'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25
User entered 'mmHg'	System	28 Dec 2020 19:42:26

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25

US3672255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:25

US3672255

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:33

US3672255

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '28 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:33

US3672255

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:24:23

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:38

US3672255

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:24:23

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:39:40
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '28 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:42:38

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	02 Feb 2021 22:08:24

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '2 Feb 2021'	Patty Howenstine (b) (4)	02 Feb 2021 22:08:24

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Clinic (Clinic)'	Patty Howenstine (b) (4)	02 Feb 2021 22:08:24

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 22:08:24

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User closed query 'Per sponsor review, this field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:38:19
Query 'Per sponsor review, this field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:39:00
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 18:38:35
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:38:35
User opened query 'Per sponsor review, this field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:53:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '23 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	02 Feb 2021 22:09:16

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:38:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:17:52

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	02 Feb 2021 22:09:16

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	08 Apr 2021 18:38:35
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	06 Mar 2021 06:17:52
	System	

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '2 Feb 2021'	(b) (4) Patty Howenstine (b) (4)	02 Feb 2021 22:09:16

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mRNA-1273 (mRNA-1273)'	Patty Howenstine (b) (4)	02 Feb 2021 22:09:16

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mRNA-1273 (mRNA-1273)'	Patty Howenstine (b) (4)	02 Feb 2021 22:09:16

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mRNA-1273 (mRNA-1273)'	Patty Howenstine (b) (4)	02 Feb 2021 22:09:16

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	02 Feb 2021 22:09:16

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	02 Feb 2021 22:09:16

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:23

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered empty.	System	02 Feb 2021 22:09:16

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	02 Feb 2021 22:10:48

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '2 Feb 2021'	Patty Howenstine (b) (4)	02 Feb 2021 22:10:48

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '13:23'	Patty Howenstine (b) (4)	02 Feb 2021 22:10:48

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:23

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '2 Feb 2021 13:23'	System	02 Feb 2021 22:10:48

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	02 Feb 2021 22:11:08

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '2 Feb 2021'	(b) (4) Patty Howenstine (b) (4)	02 Feb 2021 22:11:08

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:23

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '13:18'	Patty Howenstine (b) (4)	02 Feb 2021 22:11:08

US3672255

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:23

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:11:38
User entered '2 Feb 2021 13:18'	System	02 Feb 2021 22:11:08

US3672255

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:24:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:28
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 222 (28MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:50:44
Query 'Per DM CLR: Per Safety Follow Up Diary Day 222 (28MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:56:12
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 222 (28MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 09:26:04
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 18:04:15

US3672255

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:24:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1 - 22Sep2020; end date: Day 19 - 10Oct2020). Please review AE#2 as the stop date doesn't match with eDairy. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 18:58:47
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1 - 22Sep2020; end date: Day 19 - 10Oct2020). Please review AE#2 as the stop date doesn't match with eDairy. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'done' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:51:55
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1 - 22Sep2020; end date: Day 19 - 10Oct2020). Please review AE#2 as the stop date doesn't match with eDairy. Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 06:54:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 21:33:01

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 19:09:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 19:09:18
Data point term sent to Coder	System	13 Oct 2020 19:08:17
User entered 'HEADACHE'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '22 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 19:10:22
User entered '16:40' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 19:10:22
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 19:07:31
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
User entered '22 Sep 2020 16:40'	System	13 Oct 2020 19:10:22
User entered empty.	System	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	System	13 Oct 2020 19:10:28
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 19:10:28
User entered 'Yes (Y)'		
	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '01 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 09:44:31
User closed query 'Per CDM: Per page 32 of CCGs, This field is not required, unless end time is within 24 hours of dosing time. Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:44:25
Query 'Data is required. Please provide.' answered with 'false. query recommended to remove end time since it is not within 24 hours.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 19:47:06
Query 'Per CDM: Per page 32 of CCGs, This field is not required, unless end time is within 24 hours of dosing time. Please consider it to remove. Thank you. ' answered with 'removed' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:46:48
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:46:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 19:46:42
User opened query 'Per CDM: Per page 32 of CCGs, This field is not required, unless end time is within 24 hours of dosing time. Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:01:23
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 19:11:22
User entered '12:00' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 19:11:22
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 19:10:28
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
User entered empty.	System	27 Oct 2020 19:46:42
User entered '01 Oct 2020 12:00'	System	13 Oct 2020 19:11:22
User entered empty.	System	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Related (RELATED)'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'l'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
User entered '0'	System	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22
User entered '0'	System	13 Oct 2020 19:07:31

US3672255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:22

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
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)	05 Apr 2021 18:59:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 18:59:33
Data point term sent to Coder	System	05 Apr 2021 18:58:57
Coding entries removed.	(b) (4), (b) (6)	05 Apr 2021 18:58:33
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 18:58:33
User entered 'intermittent FATIGUE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:58:33
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	21 Dec 2020 07:31:15
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	18 Dec 2020 17:58:49
' answered with 'confirm' (Site from DM).		
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	16 Dec 2020 05:10:31
' (Site from DM).		
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)	13 Oct 2020 19:09:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 19:09:19
Data point term sent to Coder	System	13 Oct 2020 19:08:17
User entered 'FATIGUE'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '22 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 19:09:59
User entered '16:40' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 19:09:59
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 19:08:13
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
User entered '22 Sep 2020 16:40'	System	13 Oct 2020 19:09:59
User entered empty.	System	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 22:10:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '9 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 22:10:41
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Nov 2020 22:10:51
User entered '0:03' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 22:10:51
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Nov 2020 22:10:41
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
User entered '9 Oct 2020 0:03'	System	15 Nov 2020 22:10:51
User entered empty.	System	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Related (RELATED)'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'l'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	15 Nov 2020 22:10:41
Data Entry Error	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 19:10:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 19:10:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 19:10:09
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 19:08:13
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
User entered '0'	System	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28
User entered '0'	System	13 Oct 2020 19:08:13

US3672255

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:28

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:54:52
User closed query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	25 Feb 2021 15:49:07
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in ankle - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 01:02:08
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 01:02:08
Data point term sent to Coder	System	24 Feb 2021 15:44:16
Query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'done' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:43:51
Coding entries removed.	Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:43:43
User entered 'INTERMITTENT JOINT ACHES (Bilateral Ankles)' reason for change: Data Entry Error	Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:43:43
Query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with '12/28 - started illness visit' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:28:52

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
User opened query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:40:29
User opened query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.)	(b) (4), (b) (6)	14 Jan 2021 08:11:29
Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:57:59
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:57:59
Data point term sent to Coder	System	18 Dec 2020 18:06:33
Coding entries removed.	(b) (4), (b) (6)	18 Dec 2020 18:06:08
User entered 'INTERMITTENT JOINT ACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 18:06:08
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 18:44:26
Query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.'	(b) (4), (b) (6)	06 Nov 2020 21:10:43
answered with 'This is a continuation of the diary response of multiple joints' (Site from DM).		
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 08:40:43

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 19:10:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 19:10:21
Data point term sent to Coder	System	13 Oct 2020 19:09:18
User entered 'JOINT ACHES'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	13 Oct 2020 19:09:48
User entered '16:40' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 19:09:48
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 19:08:57
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 16:40'	System	13 Oct 2020 19:09:48
User entered empty.	System	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per MM, please provide the end date.'" (Site from DM).	(b) (4)	
Query 'Per MM, please provide the end date.'" answered with 'Still ongoing' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 15:52:59
User opened query 'Per MM, please provide the end date.'" (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:40:40
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 04:27:04
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:06:30
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 01:10:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Related (RELATED)'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 19:08:57

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User closed query 'Per DM CLR: Please note the stop date of this AE is sequential with the start date of AE #2. Please review if these AEs are related; and if so, combined into a single entry and ensure that start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:41:17
Query 'Per DM CLR: Please note the stop date of this AE is sequential with the start date of AE #2. Please review if these AEs are related; and if so, combined into a single entry and ensure that start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' answered with '#2 intermittent' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:58:11
User opened query 'Per DM CLR: Please note the stop date of this AE is sequential with the start date of AE #2. Please review if these AEs are related; and if so, combined into a single entry and ensure that start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:41:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 07:31:29
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'confirm' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:59:42
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:10:44
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)	15 Nov 2020 22:12:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Nov 2020 22:12:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

3233 of 3813

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	15 Nov 2020 22:12:23
User entered 'fatigue'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 21AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:49:33
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 21AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:58:03
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 18:57:57
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:57:57
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 21AUG2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:41:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '22 Aug 2020' reason for change: Data Entry Error	Patty Howenstine (b) (4)	24 Feb 2021 15:45:24
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Fatigue on 21 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 09:42:26

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Fatigue on 21 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:08:00
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 18:07:43
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Fatigue on 21 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 03:40:59
User entered '27 Aug 2020'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 09:42:29
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 18:08:10
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Dec 2020 18:07:43
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
User entered empty.	System	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '21 Sep 2020'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 09:42:33
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 18:08:15
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Dec 2020 18:07:43
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
User entered empty.	System	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	15 Nov 2020 22:11:45
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 22:11:45
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Nov 2020 22:11:40
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
User entered '0'	System	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52
User entered '0'	System	15 Nov 2020 22:11:40

US3672255

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:52

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	21 Dec 2020 07:31:34
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	18 Dec 2020 17:59:56
' answered with 'confirmed' (Site from DM).		
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	16 Dec 2020 05:10:54
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Nov 2020 22:12:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Nov 2020 22:12:48
Data point term sent to Coder	System	15 Nov 2020 22:12:23
User entered 'Generalized Joint aches'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 22:13:20
User entered '22 Sep 2020'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Nov 2020 22:13:07
User entered '13:18' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 22:13:07
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Nov 2020 22:12:21
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User entered '22 Aug 2020 13:18'	System	15 Nov 2020 22:13:20
User entered '22 Sep 2020 13:18'	System	15 Nov 2020 22:13:07
User entered empty.	System	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	15 Nov 2020 22:13:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Nov 2020 22:13:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 22:13:07
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Nov 2020 22:12:21
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	(b) (4)	15 Nov 2020 22:13:20
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	15 Nov 2020 22:12:21
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'End time is prior or equal to Start time. Please correct.' (Site from System).	(b) (4)	15 Nov 2020 22:13:20
User opened query 'End time is prior or equal to Start time. Please correct.' (Site from System).	System	15 Nov 2020 22:13:07
User entered '22:22' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 22:13:07
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User entered '15 Sep 2020 22:22'	System	15 Nov 2020 22:13:07
User entered empty.	System	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'l'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User entered '0'	System	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User entered '0'	System	15 Nov 2020 22:12:21

US3672255

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per CDM: RQ: Response noted. Please consider to provide end date .Else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:38:42
Query 'Per CDM: RQ: Response noted. Please consider to provide end date .Else clarify. Thank you. ' answered with 'OK' (Site from DM).	Patty Howenstine (b) (4)	01 Mar 2021 20:46:30
User opened query 'Per CDM: RQ: Response noted. Please consider to provide end date .Else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:44:59
User closed query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	26 Feb 2021 11:44:59
Per MM, please provide the end date." ' (Site from DM).		
Query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	Patty Howenstine (b) (4)	24 Feb 2021 15:44:20
Per MM, please provide the end date." ' answered with 'yes' (Site from DM).		
User opened query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	02 Feb 2021 12:42:17
Per MM, please provide the end date." ' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 19:50:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 19:50:22
Data point term sent to Coder	System	28 Dec 2020 19:49:35
User entered 'upper respiratory infection'	Patty Howenstine (b) (4)	28 Dec 2020 19:48:52

PRODUCTION RELEASE (v12.003
EAB) (1725)

3307 of 3813

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '24 Dec 2020'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
User entered empty.	System	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	01 Mar 2021 20:46:23
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '31 Dec 2020' reason for change: Data Entry Error	System	04 Mar 2021 20:11:00
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 20:11:00
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).		
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	01 Mar 2021 20:46:51
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Mar 2021 20:46:51
User entered '31 Dec 2021' reason for change: Data Entry Error	System	01 Mar 2021 20:46:23
User entered empty.	System	01 Mar 2021 20:46:23
	Patty Howenstine (b) (4)	01 Mar 2021 20:46:23
	(b) (4)	
	Patty Howenstine (b) (4)	28 Dec 2020 19:48:52
	(b) (4)	

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
User entered empty.	System	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 03:34:19
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 20:14:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 20:14:47
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly review and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 17:46:51
User entered 'None (NONE)'	Patty Howenstine (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'I'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Patty Howenstine (b) (4)	01 Mar 2021 20:46:51
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Patty Howenstine (b) (4)	28 Dec 2020 19:48:52
	(b) (4)	

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
User entered '0'	System	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05
User entered '0'	System	28 Dec 2020 19:48:52

US3672255

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:05

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User closed query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:40:19
Query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy.' answered with 'confirm that this is not Lymphadenopathy' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:58:56
User opened query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location and laterality of LYMPHADENOPATHY (e.g., Left Axillary Lymphadenopathy - IPSILATERAL to vaccination arm). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:41:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Axillary pain, LLT: Axillary pain - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 18:01:01
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 18:01:01
Data point term sent to Coder	System	24 Feb 2021 15:48:23
User entered 'Right axilla Pain'	Patty Howenstine (b) (4)	24 Feb 2021 15:47:24

PRODUCTION RELEASE (v12.003
EAB) (1725)

3343 of 3813

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '13 Nov 2020'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
User entered empty.	System	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '19 Nov 2020'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
User entered empty.	System	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Patty Howenstine (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Patty Howenstine (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:24:34
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'will update' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 19:08:57
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:42:01
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'I'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
User entered '0'	System	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11
User entered 'I'	System	24 Feb 2021 15:47:24

US3672255

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:11

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Soft tissue disorders NEC, PT: Groin pain, LLT: Groin pain - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:17:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:17:59
Data point term sent to Coder	System	24 Feb 2021 16:17:33
User entered 'right groin pain'	Patty Howenstine (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '13 Nov 2020'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
User entered empty.	System	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '19 Nov 2020'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
User entered empty.	System	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Patty Howenstine (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Related (NOT RELATED)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Patty Howenstine (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'I'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	24 Feb 2021 16:17:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 16:17:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Patty Howenstine (b) (4)	24 Feb 2021 16:17:02
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 16:16:56
User entered empty.	Patty Howenstine (b) (4)	24 Feb 2021 16:16:56
	(b) (4)	

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
User entered '0'	System	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21
User entered '0'	System	24 Feb 2021 16:16:56

US3672255

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:21

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 17:38:47
User entered		
'USA-US116-2021-mRNA-1273-P301000011'	System	06 Apr 2021 17:38:43
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 17:38:43

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please confirm if patient has met EC5.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 18:01:58
Query 'Per MM: please confirm if patient has met EC5.' answered with 'did not meet exclusion criteria 5 at study entry if that is what you are asking' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:10:57
User opened query 'Per MM: please confirm if patient has met EC5.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 15:49:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicidal ideation, LLT: Suicidal ideation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 19:29:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 19:29:14
Data point term sent to Coder	System	05 Apr 2021 19:25:52
User entered 'suicidal ideation'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '27 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	05 Apr 2021 19:26:37
User entered empty; reason for change Data Entry Error	System	05 Apr 2021 19:26:37
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 19:24:59
User entered '17:30'	System	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:26:37
User entered '2 Apr 2021 17:30'	System	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '27 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '2 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:17
User closed query 'PV Query: As the last dose of study drug was given on 22 Sep 2020, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:23:26
Query 'PV Query: As the last dose of study drug was given on 22 Sep 2020, please update the action taken with study drug from none to not applicable. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:01:10
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 18:00:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:00:52
User opened query 'PV Query: As the last dose of study drug was given on 22 Sep 2020, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:53:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:29:12
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:25:24
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:24:36
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'Patient has medical history including PTSD, GAD, depression' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:02:56
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'not done' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:01:43
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'not done' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:01:29
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:54:10

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:54:03
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:53:56
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'We have been trying to reach patient regarding alerts related to covid exposure and had been unable. Finally patient returned our call today to state they had been unable to respond due to hospitalization for suicidal ideation. Their psych meds were discontinued in the hospital and a new regimen begun.'	(b) (4), (b) (6)	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 19:24:59

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 19:30:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 19:30:20
Data point term sent to Coder	System	05 Apr 2021 19:27:54
User entered 'worsening depression'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '3 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Apr 2021 19:27:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 19:27:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:27:27
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:27:18
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:27:18

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 19:27:27

US3672255

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:24:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:27:18

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:24:23

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:05:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1-2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:59:15
Query 'Per DM CLR: Per Diary Dose 1 Day 1-2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'subject denies taking medication day 1-2, only on 8/25 and 8/27' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 16:21:41
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1-2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:31:18
Query 'Per DM CLR: Per Diary Dose 1 Day 1-2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 04:49:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:24:23

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1-2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 06:25:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:22:57

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:26:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:26:31
Data point term sent to Coder	System	25 Aug 2020 17:25:18
User entered 'DIAZEPAM'	(b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'ANXIETY'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '5'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'UN Apr 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:37:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:37:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:37:02
User entered '27 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:37:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:24:55

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Aug 2020 17:28:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 17:28:32
Data point term sent to Coder	System	25 Aug 2020 17:27:23
User entered 'amitriptyline'	(b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'DEPRESSION'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '25'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'UN Apr 2020'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:37:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:37:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 19:37:18
User entered '27 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:37:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 17:27:06

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:29:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:29:33
Data point term sent to Coder	System	25 Aug 2020 17:28:25
User entered 'PROZAC'	(b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'DEPRESSION'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '20'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:37:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 19:37:32
User entered '27 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:37:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 17:28:02

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 21:15:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 21:15:50
Data point term sent to Coder	System	02 Sep 2020 21:13:26
User entered 'Ibuprofen'	(b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Headache'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '400'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per CDM Re-Query. Please confirm if this Solicited Adverse Reaction meets any Event adverse reporting criteria, if so, please update the AE log. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 07:29:53
Query 'Per CDM Re-Query. Please confirm if this Solicited Adverse Reaction meets any Event adverse reporting criteria, if so, please update the AE log. Thank you' answered with 'does not meet criteria to report as AE. resolved on day 4' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:47:49
User opened query 'Per CDM Re-Query. Please confirm if this Solicited Adverse Reaction meets any Event adverse reporting criteria, if so, please update the AE log. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:04:10
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE Page as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:04:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE Page as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'solicited AE recorded by patient per eDiary for headache day on 25 AUG 2020' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 19:50:01
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE Page as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:48:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User entered '1'	System	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User entered '1'	System	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:18
User entered '804 (804)'	System	02 Sep 2020 21:12:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 21:15:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 21:15:51
Data point term sent to Coder	System	02 Sep 2020 21:14:30
User entered 'Ibuprofen'	(b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Headache'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '400'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per CDM Re-Query: Please confirm if this Solicited ADverse Reaction meets any Adverse Event Reporting Criteria. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 07:30:31
Query 'Per CDM Re-Query: Please confirm if this Solicited ADverse Reaction meets any Adverse Event Reporting Criteria. Thank you' answered with 'does not meet criteria to report as AE. resolved on day 4' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:47:56
User opened query 'Per CDM Re-Query: Please confirm if this Solicited ADverse Reaction meets any Adverse Event Reporting Criteria. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:04:50
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE Page as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:04:50

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE Page as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'This conmed is in reference to headache day recorded in eDiary by subject on 27 AUG 2020' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 19:50:57
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE Page as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:48:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User entered '1'	System	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User entered '1'	System	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:20
User entered '804 (804)'	System	02 Sep 2020 21:13:33

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 20:42:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 20:42:38
Data point term sent to Coder	System	30 Sep 2020 20:41:53
User entered 'IBUPROFEN'	(b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 03:46:12
Query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'unknown' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:11:54
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of Pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:05:01
User entered 'PAIN'	(b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '400'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'BID'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User entered empty.	System	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User entered empty.	System	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:25
User entered empty.	System	30 Sep 2020 20:41:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:33:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:33:20
Data point term sent to Coder	System	06 Oct 2020 21:32:19
User entered 'ibuprofen'	(b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'joint aches'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '400'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 21:31:21

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:33:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 21:33:21
Data point term sent to Coder	System	06 Oct 2020 21:32:19
User entered 'omeprazole'	(b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:52:05
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'fixed, added to med hx' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:47:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:01:39
User entered 'heartburn'	(b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '20'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 21:31:38

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 06:29:32
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 06:29:32
Data point term sent to Coder	System	22 Nov 2020 21:39:31
User entered 'Ibuprofen'	(b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 03:42:47
(Site from DM).		
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'	(b) (4), (b) (6)	25 Feb 2021 03:42:43
(Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'	Patty Howenstine (b) (4)	24 Feb 2021 16:17:33
answered with 'Updated AE' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'	Patty Howenstine (b) (4)	24 Feb 2021 16:17:26
answered with 'updated AE' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'	(b) (4), (b) (6)	03 Feb 2021 21:54:10
(Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'	(b) (4), (b) (6)	14 Jan 2021 14:10:28
(Site from DM).		
User entered 'Groin pain, right side'	(b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '200'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:07:48
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 19:33:28
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 19:33:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:33:04
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:42:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 19:33:04
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:33:04
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User entered '3'	System	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User entered '1'	System	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:30
User entered '804 (804)'	System	22 Nov 2020 21:39:17

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: COUGH AND COLD PREPARATIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 01:51:49
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 01:51:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:15:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:25:54
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:25:54
Data point term sent to Coder	System	12 Apr 2021 18:38:49
User closed query 'CDM-Coding: Please enter the active ingredient(s) of drug name DAYQUIL in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	System	12 Apr 2021 18:38:17
Query 'CDM-Coding: Please enter the active ingredient(s) of drug name DAYQUIL in drug name field and please make your changes to the reported term. Thank you. ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 18:38:17
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 18:37:57
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 18:37:57
User entered 'DAYQUIL (ingredients unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:37:57

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

Name of Medication

Audit	User	Time (GMT)
User opened query 'CDM-Coding: Please enter the active ingredient(s) of drug name DAYQUIL in drug name field and please make your changes to the reported term. Thank you. ' (Site from System). User signature succeeded.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:28:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL - version WHODrug-Global-B3\\202003.	Cynthia Strout (b) (4) (b) (4) Coder Import (b) (4) (b) (4)	05 Mar 2021 18:04:15 28 Dec 2020 19:46:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Dec 2020 19:46:23
Data point term sent to Coder User entered 'dayquil'	System Patty Howenstine (b) (4) (b) (4)	28 Dec 2020 19:45:21 28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'upper respiratory infection'	Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '2'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'tablet (TABLET)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'twice daily (BID)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '26 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:51:13
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 19:35:51
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 19:35:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:35:44
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:40:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	28 Dec 2020 19:47:36
User entered 'No (N)'	Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 19:35:44
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:35:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
	(b) (4)	
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	28 Dec 2020 19:47:36
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	28 Dec 2020 19:45:09
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:45:09
	(b) (4)	

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User entered '2'	System	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User entered '1'	System	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:34
User entered '804 (804)'	System	28 Dec 2020 19:45:09

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ANILIDES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 13:48:54
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 13:48:54
Data point term sent to Coder	System	12 Apr 2021 18:38:48
User closed query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	12 Apr 2021 18:38:47
Query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'updated' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 18:38:47
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 18:38:41
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 18:38:41
User entered 'NYQUIL (ingredients unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 18:38:41
User opened query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	06 Apr 2021 14:56:50
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 19:47:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 19:47:29
Data point term sent to Coder	System	28 Dec 2020 19:46:21
User entered 'Nyquil'	Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 19:45:46
User entered 'upper respiratory infection' reason for change: Data Entry Error	System	28 Dec 2020 19:45:46
User opened query 'Data is required. Please complete.' (Site from System).	Patty Howenstine (b) (4)	28 Dec 2020 19:45:35
User entered empty.	(b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '2'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'tablet (TABLET)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'once daily (QD)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Oral (ORAL)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered empty.	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '26 Dec 2020'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered '0'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:51:25
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 19:36:22
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 19:36:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:36:16
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:40:56
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 19:36:16
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 19:36:16
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
	(b) (4)	
User entered empty.	Patty Howenstine (b) (4)	28 Dec 2020 19:45:35
	(b) (4)	

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:04:15
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User entered '1'	System	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User entered '1'	System	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:29:37
User entered '804 (804)'	System	28 Dec 2020 19:45:35

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 12:19:56
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:19:56
Data point term sent to Coder	System	05 Apr 2021 19:39:19
User entered 'gabapentin'	(b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'intermittent joint aches'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '3600'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '28 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:39:04

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: PAROXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PAXIL [PAROXETINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:10:39
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:10:39
Data point term sent to Coder	System	05 Apr 2021 19:40:20
User entered 'paxil'	(b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'worsening depression; suicidal ideation'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '40'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '28 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:39:42

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL, PRODUCTSYNONYM: ZESTRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 15:00:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 15:00:13
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	15 Apr 2021 14:59:14 15 Apr 2021 14:58:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL, PRODUCTSYNONYM: ZESTRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:40:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:40:52
Data point term sent to Coder User entered 'zestril'	System (b) (4), (b) (6)	05 Apr 2021 19:40:19 05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 14:58:14
User entered 'Hypertension' reason for change: Per Query Resolution	System	15 Apr 2021 14:58:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 14:58:14
User entered empty.	System	05 Apr 2021 19:40:10
	(b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '5'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '28 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:40:10

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 15:01:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 15:01:55
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	15 Apr 2021 15:01:16 15 Apr 2021 15:00:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:42:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:42:32
Data point term sent to Coder User entered 'lipitor'	System (b) (4), (b) (6)	05 Apr 2021 19:41:24 05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 15:00:58
User entered 'hyperlipidemia' reason for change: Per Query Resolution	System	15 Apr 2021 15:00:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 15:00:58
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '20'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'every other day (QOD)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '28 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:40:40

US3672255

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:24:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:42:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:59:15

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'USA-US116-2021-MRNA-1273-P301000011'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Yes (Y)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Yes (Y)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Yes (Y)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Cynthia'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Strout'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:43:00
User closed query 'Please update with the most recent address.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 14:42:36
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:36:01
Query 'Please update with the most recent address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:33:21
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User entered '4920 O'Hear Ave, Suite 101' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User opened query 'Please update with the most recent address.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:12:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered '1156 Bowman Road'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:43:25
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:36:01
Un-reviewed for Safety.	(b) (4)	22 Apr 2021 13:33:01
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User entered 'N Charleston' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:33:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4)	06 Apr 2021 17:39:02
User entered 'Mount Pleasant'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered empty.	(b) (4)	12 Apr 2021 16:31:56
User entered 'SC'	System	09 Apr 2021 18:02:15
	(b) (4), (b) (6)	

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:43:38
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:36:01
Un-reviewed for Safety.	(b) (4)	22 Apr 2021 13:33:01
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User entered '29405' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:33:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:12:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4)	06 Apr 2021 17:39:02
User entered '29464'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered 'US'	(b) (4) System	06 Apr 2021 17:39:10

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 16:31:56
User entered '1'	System	06 Apr 2021 17:39:10

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'USA-US116-2021-MRNA-1273-P301000011'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Yes (Y)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Yes (Y)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Yes (Y)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Cynthia'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Strout'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:43:00
User closed query 'Please update with the most recent address.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 14:42:36
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:36:01
Query 'Please update with the most recent address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:33:21
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User entered '4920 O'Hear Ave, Suite 101' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User opened query 'Please update with the most recent address.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:12:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered '1156 Bowman Road'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:43:25
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:36:01
Un-reviewed for Safety.	(b) (4)	22 Apr 2021 13:33:01
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User entered 'N Charleston' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:33:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4)	06 Apr 2021 17:39:02
User entered 'Mount Pleasant'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered empty.	(b) (4)	12 Apr 2021 16:31:56
User entered 'SC'	System	09 Apr 2021 18:02:15
	(b) (4), (b) (6)	

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:43:38
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:36:01
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User entered '29405' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:33:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:12:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered '29464'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered 'US'	(b) (4) System	06 Apr 2021 17:39:10

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 16:31:56
User entered '1'	System	06 Apr 2021 17:39:10

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:24:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered '06/Apr/2021 12:39'	(b) (4) System	06 Apr 2021 17:39:10

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:24:23

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)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 17:39:10

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'USA-US116-2021-MRNA-1273-P301000011'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Yes (Y)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Yes (Y)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Yes (Y)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'No (N)'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Cynthia'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered 'Strout'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:43:00
User closed query 'Please update with the most recent address.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 14:42:36
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:36:01
Query 'Please update with the most recent address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:33:21
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User entered '4920 O'Hear Ave, Suite 101' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User opened query 'Please update with the most recent address.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:12:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:39:02
User entered '1156 Bowman Road'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:43:25
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:36:01
Un-reviewed for Safety.	(b) (4)	22 Apr 2021 13:33:01
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User entered 'N Charleston' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:33:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:12:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4)	06 Apr 2021 17:39:02
User entered 'Mount Pleasant'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered empty.	(b) (4)	12 Apr 2021 16:31:56
User entered 'SC'	System	09 Apr 2021 18:02:15
	(b) (4), (b) (6)	

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:43:38
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:36:01
Un-reviewed for Safety.	(b) (4)	22 Apr 2021 13:33:01
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:33:01
User entered '29405' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:33:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:12:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
Reviewed for Safety.	(b) (4)	06 Apr 2021 17:39:02
User entered '29464'	System	06 Apr 2021 17:38:43

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered 'US'	(b) (4) System	06 Apr 2021 17:39:10

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Apr 2021 16:31:56
User entered '1'	System	06 Apr 2021 17:39:10

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:24:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered '12/Apr/2021 09:31'	(b) (4) System	12 Apr 2021 16:31:56

US3672255

Folder: SAE USA-US116-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:24:23

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)	19 Apr 2021 17:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:15:52
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 16:31:56