

US3572125 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:15:18

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US3572125

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 04:30:12

Generated On: 10 Jun 2021 08:15:18

[Participant ID](#)

US3572125

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

US3572125

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3572125

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 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 type="radio"/>
	Amendment 3 <input checked="" 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Condition	LOW TESTOSTERONE
Start date (dd MMM yyyy)	UN JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Condition	DANDRUFF
Start date (dd MMM yyyy)	UN JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Condition	HERPES SIMPLEX II
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Condition	ONE KIDNEY BIRTH DEFECT
Start date (dd MMM yyyy)	(b) (6) 1978
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)	(b) (6) 1978
Start Year (derived)	1978
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3572125

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Condition	PSORIASIS
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)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Condition	SUBJECT REALIZED THEY HAD A WART ON THEIR FOOT. ON 08 SEP. 2020, THEY HAD IT REMOVED PER DOCTORS RECOMMENDATION
Start date (dd MMM yyyy)	1 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	8 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:00
Height (xxx.x)	72 in
Weight (xxx.x)	185 lb
BMI (xxx.x)	25.14297 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	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 (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:34:27

Generated On: 10 Jun 2021 08:15:18

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 111593

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

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)	3 SEP 2020
Time of assessment (00:00-23:59)	14:11 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:11
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Height	ND - Not Done
Weight	ND - Not Done
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)	3 SEP 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 15:00
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="checkbox"/> Axillary <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If Other, specify	TEMPORAL
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 14:30 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 14:30

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	14:14 (24 HR)
Collection date and time (derived)	3 SEP 2020 14:14

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:20	3 SEP 2020 14:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:00

PC Open Date & Time

03 SEP 2020 14:50

PC Close Date & Time

03 SEP 2020 17:20

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.4 °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	03 SEP 2020 21:21
PC Open Date & Time	03 SEP 2020 18:15
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 21:35

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 21:27

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

98.1 °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

07 SEP 2020 00:12

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

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

07 SEP 2020 22:16

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

98.4 °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

08 SEP 2020 22:03

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 22:16

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

03 SEP 2020 15:01

PC Open Date & Time

03 SEP 2020 14:50

PC Close Date & Time

03 SEP 2020 17:20

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:22

PC Open Date & Time

03 SEP 2020 18:15

PC Close Date & Time

04 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

04 SEP 2020 21:39

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

05 SEP 2020 21:28

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 00:13

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

07 SEP 2020 22:16

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

08 SEP 2020 22:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

09 SEP 2020 22:16

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 15:01
PC Open Date & Time	03 SEP 2020 14:50
PC Close Date & Time	03 SEP 2020 17:20

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 21:23
PC Open Date & Time	03 SEP 2020 18:15
PC Close Date & Time	04 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

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EAB) (1725)

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 21:40
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

53 of 2732

EAB) (1725)

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:29
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

55 of 2732

EAB) (1725)

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 00:13
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

57 of 2732

EAB) (1725)

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 22:17
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

59 of 2732

EAB) (1725)

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:04
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

61 of 2732

EAB) (1725)

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 22:17
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3572125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	VISIT2

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

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)	02 OCT 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 13:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

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)	02 OCT 2020
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 14:09
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3572125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 13:39 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 13:39

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

US3572125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 OCT 2020
Collection time (00:00-23:59)	13:11 (24 HR)
Collection date and time (derived)	02 OCT 2020 13:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:04	02 OCT 2020 13:04
Nasopharyngeal Swab 2	No		

US3572125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 14:07

PC Open Date & Time

02 OCT 2020 13:59

PC Close Date & Time

02 OCT 2020 16:29

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 02 OCT 2020 21:53

PC Open Date & Time 02 OCT 2020 17:24

PC Close Date & Time 03 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

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	100.2 °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	03 OCT 2020 20:57
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

99.3 °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):

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

04 OCT 2020 22:02

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

98.6 °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

05 OCT 2020 21:39

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

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

06 OCT 2020 21:11

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 22:34

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 22:55

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

02 OCT 2020 14:07

PC Open Date & Time

02 OCT 2020 13:59

PC Close Date & Time

02 OCT 2020 16:29

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 21:54

PC Open Date & Time

02 OCT 2020 17:24

PC Close Date & Time

03 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

03 OCT 2020 21:03

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

04 OCT 2020 22:03

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	05 OCT 2020 21:40
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

06 OCT 2020 21:12

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

07 OCT 2020 22:34

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

08 OCT 2020 22:56

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 14:08
PC Open Date & Time	02 OCT 2020 13:59
PC Close Date & Time	02 OCT 2020 16:29

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 21:55
PC Open Date & Time	02 OCT 2020 17:24
PC Close Date & Time	03 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

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EAB) (1725)

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 21:05
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

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EAB) (1725)

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 22:04
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 21:41
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 21:13
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

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EAB) (1725)

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 22:34
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

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 ☒

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 22:57
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 09 OCT 2020 19:58

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 10 OCT 2020 20:52

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:15:18

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 11 OCT 2020 20:50

PC Open Date & Time 11 OCT 2020 12:00

PC Close Date & Time 12 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:15:18

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	09 OCT 2020 19:58
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:15:18

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	10 OCT 2020 20:52
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:15:18

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	11 OCT 2020 20:51
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3572125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 NOV 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

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 NOV 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 10:40
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3572125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 NOV 2020
Collection time (00:00-23:59)	10:50 (24 HR)
Collection date and time (derived)	6 NOV 2020 10:50

US3572125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:12:08

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 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"/>

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	24 NOV 2020 19:31:47
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 14:30:48
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 14:29:32
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	15 DEC 2020 11:26:59
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 <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	19 DEC 2020 10:49:17
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

26 DEC 2020 00:21:21

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 00:05:09
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 05:39:02

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 <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	17 JAN 2021 16:59:12
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 12:00:55

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 10:02:24

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 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	06 FEB 2021 19:10:25
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 00:01:59
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

20 FEB 2021 22:55:16

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 16:38:08

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 10:56:55
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 10:42:00

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 15:25:08
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 20:37:09

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 21:24:54

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 13:53:42

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

18 APR 2021 17:47:54

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 15:37:17
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

02 MAY 2021 18:54:34

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 <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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 <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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 <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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 <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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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="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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 <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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 <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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 <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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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="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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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"/>
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Date and time of submission

Patient Cloud Open Date & Time	15 OCT 2022 00:01
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Patient Cloud Close Date & Time	19 OCT 2022 23:59
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US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3572125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:15:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 16:37:54

US3572125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:14:59

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:14:59

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 19:14:13

Generated On: 10 Jun 2021 08:15:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 19:14:13

Generated On: 10 Jun 2021 08:15:18

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3572125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 19:14:13

Generated On: 10 Jun 2021 08:15:18

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.

US3572125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 19:14:13

Generated On: 10 Jun 2021 08:15:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 APR 2021
Collection time (00:00-23:59)	15:10 (24 HR)
Collection date and time (derived)	8 APR 2021 15:10

US3572125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:14:13

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572125

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572125

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

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

US3572125

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

Date of Contact	03 FEB 2021
Time of Contact	14:30
Date and Time of Contact (derived)	03 FEB 2021 14:30
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>

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	01 FEB 2021
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	97.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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 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"/>

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 FEB 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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)

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US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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 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"/>

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 FEB 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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	4 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	97 %
---------------	------

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

Temperature	98.2 F
-------------	--------

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

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

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

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

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Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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"/>

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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	5 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

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

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

Temperature	97.4 F
-------------	--------

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

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

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

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

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Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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	6 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

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

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

Temperature	97.0 F
-------------	--------

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

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

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

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

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Generated On: 10 Jun 2021 08:15:18

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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"/>

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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	7 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

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

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

Temperature	97.7 F
-------------	--------

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

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

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

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

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Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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"/>

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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"/>

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	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	8 FEB 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	97 %
---------------	------

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

Temperature	96.7 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

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

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

Date of Visit	03 FEB 2021
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	03 FEB 2021
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

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Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

Date of Contact	10 SEP 2020
Time of Contact	13:40
Date and Time of Contact (derived)	10 SEP 2020 13:40
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3572125

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3572125

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

Date of Contact	18 SEP 2020
Time of Contact	13:20
Date and Time of Contact (derived)	18 SEP 2020 13:20
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3572125

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 03 Apr 2021 04:30:24

Generated On: 10 Jun 2021 08:15:18

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3572125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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	SICKD1

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 FEB 2021
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 16:45
Height (xxx.x)	70 in
Weight (xxx.x)	195 lb
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572125

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 FEB 2021

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

US3572125

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

03 FEB 2021

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

Was this visit performed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input type="radio"/>

Folder OID	SICKD28
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US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

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.

US3572125

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3572125

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	15 FEB 2021
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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
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US3572125

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Date of updated informed consent (dd MMM yyyy) 15 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) 15 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 _____

US3572125

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 FEB 2021

Collection time (00:00-23:59)

13:02 (24 HR)

Collection date and time (derived)

15 FEB 2021 13:02

US3572125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 FEB 2021
Collection time (00:00 - 23:59)	13:00
Collection Date and Time (derived)	15 FEB 2021 13:00

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 Apr 2021 04:30:12

Generated On: 10 Jun 2021 08:15:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 02:24:18

Generated On: 10 Jun 2021 08:15:18

AEID

Adverse event

HERPES SIMPLEX OUTBREAK-
WORSENING

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)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 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 ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 02:24:18

Generated On: 10 Jun 2021 08:15:18

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 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 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)	

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 05 Apr 2021 02:24:18

Generated On: 10 Jun 2021 08:15:18

AEID

Adverse event

HERPES SIMPLEX FLARE UP

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)

10 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)

17 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 05 Apr 2021 02:24:18

Generated On: 10 Jun 2021 08:15:18

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 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	VALTEX
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 05 Apr 2021 02:24:18

Generated On: 10 Jun 2021 08:15:18

AEID	USA-US091-2021-MRNA-1273-P30 1000010
Adverse event	ALCOHOL WITHDRAWALS
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)	10 JAN 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)	13 JAN 2021
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 checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	13 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 05 Apr 2021 02:24:18

Generated On: 10 Jun 2021 08:15:18

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	

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 05 Apr 2021 02:24:18

Generated On: 10 Jun 2021 08:15:18

SUBJECT HAS HISTORY OF ALCOHOL ABUSE, PRESENTED TO THE ED COMPLAINING OF NAUSEA, HEADACHE, AND HAND TREMORS. PATIENT WAS ADMITTED WITH THE DIAGNOSIS OF ALCOHOL WITHDRAWAL. HE WAS STARTED ON LIBRIUM 25MG PO TID, VITAMINS, AND IV FLUIDS. SUBJECT SYMPTOMS WERE RELIEVED AND PATIENT WAS DISCHARGED HOME ON LIBRIUM 25 MG PO BIDX 5 DAYS, HE WAS ADVISED TO QUIT DRINKING.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

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

Yes ☒

No ☐

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

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication CETIRIZINE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2013	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 18:23:15

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 18:23:15

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	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)	1 JAN 2017	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication AZELISTINE HCL

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 1

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

If dose unit is Other, specify SPRAY

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 AUG 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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication VALCYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication HERPES SIMPLEX II

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 18:23:15

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	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)	1 JAN 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	3 MAR 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication KETOCANAZOLE

Prophylaxis Yes ☐
No ☒

Indication DANDRUFF

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)		1 JUL 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 18:23:15

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Name of Medication TESTOSTERONE CYPIONATE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	14 JAN 2021	
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 checked="" type="radio"/> 804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 18:23:15

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Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GERD

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)	1 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 1

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

If dose unit is Other, specify SPRAY

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 AUG 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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication FEVER, PAIN (HEADACHE AND
GENERAL JOINT ACHE)

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		4 OCT 2020
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication VALTREX

Prophylaxis Yes ☐
No ☒

Indication HERPES SIMPLEX FLARE UP

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)		10 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)		18 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication VALTREX

Prophylaxis Yes ☐
No ☒

Indication HERPES SIMPLEX FLARE UP

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 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"/>

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication HPV VACCINE

Prophylaxis Yes ☒
No ☐

Indication HERPES SIMPLEX PREVENTION

Dose per administration 1

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

If dose unit is Other, specify DOSE

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication HPV VACCINE

Prophylaxis Yes ☒
No ☐

Indication HPV PREVENTION

Dose per administration 1

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

If dose unit is Other, specify DOSE

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication ZYRTEC D (CERTRIZINE
HCL/PSEUDOEPHEDRINE)

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 5/120

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication LIBRIUM

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWS

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)		10 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 JAN 2021
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication VITAMINS

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWS

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)	10 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	13 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication IV FLUID

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWS

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	13 JAN 2021	
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"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication LIBIRIUM

Prophylaxis Yes ☐
No ☒

Indication ALCOHOL WITHDRAWS

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)	13 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	12 MAR 2021	
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 checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 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 checked="" type="radio"/>
	804	<input type="radio"/>

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication XYZAL

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

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)

436 of 2732

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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)		3 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"/>

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

Name of Medication _____

Prophylaxis Yes ☐
No ☐

Indication _____

Dose per administration _____

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)

438 of 2732

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 18:23:15

Generated On: 10 Jun 2021 08:15:18

	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) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input 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"/>

US3572125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3572125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 04:30:13

Generated On: 10 Jun 2021 08:15:18

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 SEP 2020	WART REMOVAL- DERMATOLOGY	Other	SCHEDULED PREVIOUSLY

US3572125

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:15:18

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

US3572125

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:15:18

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 ☐

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

SAEID	USA-US091-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

SAEID	USA-US091-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/FEB/2021 14:12
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

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

SAEID	USA-US091-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/FEB/2021 15:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

SAEID	USA-US091-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/MAR/2021 11:54
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

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 03 Apr 2021 04:30:25

Generated On: 10 Jun 2021 08:15:18

SAEID	USA-US091-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/MAR/2021 11:30
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

US3572125 (Prod: Laguna Clinical Research Associates)

US3572125

Form: Participant Creation

Generated On: 10 Jun 2021 08:15:18

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'US3572125'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:49:44

US3572125

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User closed query 'Re-Query : Please complete the MEDICAL HISTORY, VITAL SIGNS, PHYSICAL EXAMINATION & RISK OF EXPOSURE forms. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 10:08:19
Query 'Re-Query : Please complete the MEDICAL HISTORY, VITAL SIGNS, PHYSICAL EXAMINATION & RISK OF EXPOSURE forms. Thank you.' answered with 'Completed' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 17:43:34
User opened query 'Re-Query : Please complete the MEDICAL HISTORY, VITAL SIGNS, PHYSICAL EXAMINATION & RISK OF EXPOSURE forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:58:20
User closed query 'Per CDM: please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:57:17
Query 'Per CDM: please complete all applicable forms for this visit.' answered with 'data updated ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:32:29
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:31:45
User opened query 'Per CDM: please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 11:51:02

US3572125

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:49:45

US3572125

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:31:45

US3572125

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User entered 'SCRN'	System	03 Sep 2020 19:31:45

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered (b) (6) 1978'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:49:46

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '41'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'YEARS'	System	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '41'	System	03 Sep 2020 19:38:54

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Male (M)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:15:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:33

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '27 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:54

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Aug 2020'	System	03 Sep 2020 19:38:54

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '2020'	System	03 Sep 2020 19:38:54

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Amendment 3 (3)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:54

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:38:54

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:38:54

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:38:54

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:38:54

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 19:49:45

US3572125

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:15:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'I'	System	03 Sep 2020 19:39:02

US3572125

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:39:02

US3572125

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:15:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:04:42

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 18:06:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 18:06:48
Data point term sent to Coder	System	30 Sep 2020 18:06:28
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'UN UNK 2015'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Jan 2015'	System	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '2015'	System	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:05:49

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 18:09:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 18:09:55
Data point term sent to Coder	System	30 Sep 2020 18:08:39
User entered 'LOW TESTOSTERONE'	(b) (4), (b) (6)	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'UN Jul 2020'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Jul 2020'	System	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '2020'	System	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:08:20

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Scaly conditions, PT: Dandruff, LLT: Dandruff - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 18:11:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 18:11:49
Data point term sent to Coder	System	30 Sep 2020 18:10:42
User entered 'DANDRUFF'	(b) (4), (b) (6)	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'UN Jul 2020'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Jul 2020'	System	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '2020'	System	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:09:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 18:12:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 18:12:49
Data point term sent to Coder	System	30 Sep 2020 18:11:43
User entered 'INSOMNIA'	(b) (4), (b) (6)	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'UN UNK 2015'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Jan 2015'	System	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '2015'	System	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:10:50

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type II - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 18:12:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 18:12:48
Data point term sent to Coder	System	30 Sep 2020 18:11:43
User entered 'HERPES SIMPLEX II'	(b) (4), (b) (6)	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'UN UNK 2013'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Jan 2013'	System	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '2013'	System	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:11:27

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 18:13:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 18:13:50
Data point term sent to Coder	System	30 Sep 2020 18:12:44
User entered 'ALLERGIC RHINITIS'	(b) (4), (b) (6)	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'UN UNK 2013'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Jan 2013'	System	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '2013'	System	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:11:52

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User coded data point as SOC: Psychiatric disorders, HLT: Substance related and addictive disorders, PT: Alcoholism, LLT: Alcoholism - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 18:13:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 18:13:51
Data point term sent to Coder	System	30 Sep 2020 18:12:44
User entered 'ALCOHOLISM'	(b) (4), (b) (6)	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'UN UNK 2018'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Jan 2018'	System	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '2018'	System	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:12:39

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Renal and urinary tract disorders congenital, HLT: Renal disorders congenital, PT: Congenital renal disorder, LLT: Congenital renal disorder - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 11:23:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 11:23:52
Data point term sent to Coder	System	30 Sep 2020 18:14:51
User entered 'ONE KIDNEY BIRTH DEFECT'	(b) (4), (b) (6)	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered (b) (6) 1978'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered (b) (6) 1978'	System	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '1978'	System	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:13:50

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 18:15:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 18:15:53
Data point term sent to Coder	System	30 Sep 2020 18:14:52
User entered 'PSORIASIS'	(b) (4), (b) (6)	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'UN UNK 2000'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Jan 2000'	System	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered '2000'	System	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered empty.	System	30 Sep 2020 18:14:20

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Papilloma excision, LLT: Wart excision - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 09:46:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 09:46:45
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
Data point term sent to Coder	System (b) (4)	08 Feb 2021 21:42:31
User entered 'Subject realized they had a wart on their foot. On 08 Sep. 2020, they had it removed per doctors recommendation' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 21:42:23
Data point term sent to Coder	System	08 Feb 2021 21:39:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
Data point term sent to Coder	System	08 Feb 2021 19:20:16
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
Data point term sent to Coder	System	08 Feb 2021 19:19:15
User entered 'Wart Removal - Dermatology'	(b) (4), (b) (6)	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	08 Feb 2021 21:42:23
User entered '1 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 21:42:23
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	08 Feb 2021 21:39:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	08 Feb 2021 19:19:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	08 Feb 2021 19:18:41
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User entered 'Aug 2020'	System	08 Feb 2021 21:42:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
User entered 'Sep 2020'	System	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
User entered '2020'	System	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
User entered 'Sep 2020'	System	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:15:18

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Feb 2021 21:39:09
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	08 Feb 2021 19:19:57
User entered '2020'	System	08 Feb 2021 19:18:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (u) (4), (b) (6)	06 Oct 2020 07:05:03
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered with 'DATE CORRECT ' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 18:17:07
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Sep 2020 18:15:41
User entered '3 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '14:00'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User entered '3 Sep 2020 14:00'	System	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '72' in reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	30 Sep 2020 18:19:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Sep 2020 18:15:41
DataPoint set to visible.	System	03 Sep 2020 19:39:02

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '185' lb reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	30 Sep 2020 18:19:14
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Sep 2020 18:15:41
DataPoint set to visible.	System	03 Sep 2020 19:39:02

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User entered '25.14297'	System	30 Sep 2020 18:19:14
User entered empty.	System	30 Sep 2020 18:15:41
DataPoint set to visible.	System	03 Sep 2020 19:39:02

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User entered 'kg/m2'	System	30 Sep 2020 18:19:14
User entered empty.	System	30 Sep 2020 18:15:41
DataPoint set to visible.	System	03 Sep 2020 19:39:02

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User entered 'bpm'	System	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User entered 'breaths/min'	System	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User entered 'mmHg'	System	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User entered 'mmHg'	System	30 Sep 2020 18:15:41

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16

US3572125

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16

US3572125

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:17:42

US3572125

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:21:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '3 Sep 2020'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:17:42

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

[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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

[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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered 'l'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:15:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:16
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:34:28
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:18:22

US3572125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:39:17

US3572125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:39:17

US3572125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:39:17

US3572125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'VISIT1'	System	03 Sep 2020 19:39:17

US3572125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:09:39

US3572125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '111593'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:09:39

US3572125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:09:39

US3572125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:18

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Dec 2020 17:44:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 17:44:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 17:44:16
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 18:03:47
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 18:03:47

US3572125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:18

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	03 Dec 2020 17:44:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 17:44:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 17:44:16
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 18:03:47
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 18:03:47

US3572125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Dec 2020 17:44:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 17:44:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 17:44:16
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 18:03:47
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 18:03:47

US3572125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:18

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Dec 2020 17:44:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 17:44:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 17:44:16
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 18:03:47
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 18:03:47

US3572125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Dec 2020 17:44:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 17:44:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 17:44:16
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 18:03:47
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 18:03:47

US3572125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:15:18

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Dec 2020 17:44:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 17:44:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 17:44:16
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 18:03:47
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 18:03:47
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:20:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:20:15

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '3 Sep 2020'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '14:11'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '3 Sep 2020 14:11'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '97.9' F	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'TEMPORAL'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '71'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'bpm'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '18'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'breaths/min'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '124'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '80'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:15:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered missing code ND - Not Done.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '3 Sep 2020'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '15:00'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '3 Sep 2020 15:00'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '97.5' F	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'TEMPORAL'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '67'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'bpm'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '18'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'breaths/min'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '124'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '79'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	30 Sep 2020 18:22:26

US3572125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:33

US3572125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:33

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '14:30'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '3 Sep 2020 14:30'	System	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'ONCE'	System	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:39:48

US3572125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:52

US3572125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '3 Sep 2020'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:52

US3572125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '14:14'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:22:52

US3572125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '3 Sep 2020 14:14'	System	30 Sep 2020 18:22:52

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '3 Sep 2020'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:23:06

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	30 Sep 2020 18:23:06

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:23:06

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '14:20'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:23:06

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '3 Sep 2020 14:20'	System	30 Sep 2020 18:23:06

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:15:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	30 Sep 2020 18:23:06

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:23:06

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:15:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:23:06

US3572125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered empty.	System	30 Sep 2020 18:23:06

US3572125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:29:31

US3572125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'I'	System	18 Sep 2020 17:29:31

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T14:59:43', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e7578a2b-9009-4afd-a9f8-a52228ceb231'	System	03 Sep 2020 20:00:09
User entered 'Yes (Y)'	System	03 Sep 2020 20:00:09

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T14:59:50', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e7578a2b-9009-4afd-a9f8-a52228ceb231'	System	03 Sep 2020 20:00:09
User entered '97.5'	System	03 Sep 2020 20:00:09

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T14:59:56', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e7578a2b-9009-4afd-a9f8-a52228ceb231'	System	03 Sep 2020 20:00:09
User entered 'No (N)'	System	03 Sep 2020 20:00:09

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:00:01', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e7578a2b-9009-4afd-a9f8-a52228ceb231'	System	03 Sep 2020 20:00:09
User entered '03 Sep 2020 15:00'	System	03 Sep 2020 20:00:09

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '03 Sep 2020 14:50'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '03 Sep 2020 17:20'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:21:17', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8efbf06e-c223-4644-9ea8-f81dc129bcae'	System	04 Sep 2020 02:21:47
User entered 'Yes (Y)'	System	04 Sep 2020 02:21:47

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:21:26', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8efbf06e-e223-4644-9ea8-f81dc129bcae'	System	04 Sep 2020 02:21:47
User entered '98.4'	System	04 Sep 2020 02:21:47

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:21:33', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8efbf06e-c223-4644-9ea8-f81dc129bcae'	System	04 Sep 2020 02:21:47
User entered 'No (N)'	System	04 Sep 2020 02:21:47

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:21:44', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8efbf06e-c223-4644-9ea8-f81dc129bcae'	System	04 Sep 2020 02:21:47
User entered '03 Sep 2020 21:21'	System	04 Sep 2020 02:21:47

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '03 Sep 2020 18:15'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 2'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:35:04', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd08cc31a-9acc-4540-acad-606cf302314a'	System	05 Sep 2020 02:35:35
User entered 'Yes (Y)'	System	05 Sep 2020 02:35:35

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:35:13', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd08cc31a-9acc-4540-acad-606cf302314a'	System	05 Sep 2020 02:35:35
User entered '98.7'	System	05 Sep 2020 02:35:35

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:35:22', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd08cc31a-9acc-4540-acad-606cf302314a'	System	05 Sep 2020 02:35:35
User entered 'No (N)'	System	05 Sep 2020 02:35:35

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:35:30', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd08cc31a-9ace-4540-acad-606cf302314a'	System	05 Sep 2020 02:35:35
User entered '04 Sep 2020 21:35'	System	05 Sep 2020 02:35:35

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 3'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:26:03', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '423a6566-a88f-4691-ac54-d5a7e1bdd496'	System	06 Sep 2020 02:27:27
User entered 'Yes (Y)'	System	06 Sep 2020 02:27:27

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:27:10', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '423a6566-a88f-4691-ac54-d5a7e1bdd496'	System	06 Sep 2020 02:27:27
User entered '98.7'	System	06 Sep 2020 02:27:27

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:27:15', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '423a6566-a88f-4691-ac54-d5a7e1bdd496'	System	06 Sep 2020 02:27:27
User entered 'No (N)'	System	06 Sep 2020 02:27:27

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:27:24', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '423a6566-a88f-4691-ac54-d5a7e1bdd496'	System	06 Sep 2020 02:27:27
User entered '05 Sep 2020 21:27'	System	06 Sep 2020 02:27:27

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 4'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:12:28', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5619aeda-f675-43e0-a781-8bff16253a32'	System	07 Sep 2020 05:12:56
User entered 'Yes (Y)'	System	07 Sep 2020 05:12:56

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:12:34', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5619aeda-f675-43e0-a781-8bff16253a32'	System	07 Sep 2020 05:12:56
User entered '98.1'	System	07 Sep 2020 05:12:56

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:12:38', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5619aeda-f675-43e0-a781-8bff16253a32'	System	07 Sep 2020 05:12:56
User entered 'No (N)'	System	07 Sep 2020 05:12:56

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:12:51', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5619aeda-f675-43e0-a781-8bff16253a32'	System	07 Sep 2020 05:12:56
User entered '07 Sep 2020 00:12'	System	07 Sep 2020 05:12:56

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 5'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:15:46', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '887cb16b-dc5e-4925-b60b-ab40e75f18cd'	System	08 Sep 2020 03:16:11
User entered 'Yes (Y)'	System	08 Sep 2020 03:16:11

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:15:53', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '887cb16b-dc5e-4925-b60b-ab40e75f18cd' User entered '98.8'	System	08 Sep 2020 03:16:11
	System	08 Sep 2020 03:16:11

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:15:57', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '887cb16b-dc5e-4925-b60b-ab40e75f18cd'	System	08 Sep 2020 03:16:11
User entered 'No (N)'	System	08 Sep 2020 03:16:11

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:06', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '887cb16b-dc5e-4925-b60b-ab40e75f18cd'	System	08 Sep 2020 03:16:11
User entered '07 Sep 2020 22:16'	System	08 Sep 2020 03:16:11

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 6'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:03:20', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '456e9d37-cac4-49f0-b6c1-6c070a9aa847'	System	09 Sep 2020 03:03:48
User entered 'Yes (Y)'	System	09 Sep 2020 03:03:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:03:25', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '456e9d37-cac4-49f0-b6c1-6c070a9aa847'	System	09 Sep 2020 03:03:48
User entered '98.4'	System	09 Sep 2020 03:03:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:03:29', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '456e9d37-cac4-49f0-b6c1-6c070a9aa847'	System	09 Sep 2020 03:03:48
User entered 'No (N)'	System	09 Sep 2020 03:03:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:03:42', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '456e9d37-cac4-49f0-b6c1-6c070a9aa847'	System	09 Sep 2020 03:03:48
User entered '08 Sep 2020 22:03'	System	09 Sep 2020 03:03:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 7'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:16:10', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a6040b4b-c727-4580-a976-98add8885a3f'	System	10 Sep 2020 03:16:31
User entered 'Yes (Y)'	System	10 Sep 2020 03:16:31

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:16:15', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a6040b4b-c727-4580-a976-98add8885a3f' User entered '98.6'	System	10 Sep 2020 03:16:31
	System	10 Sep 2020 03:16:31

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:16:20', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a6040b4b-c727-4580-a976-98add8885a3f'	System	10 Sep 2020 03:16:31
User entered 'No (N)'	System	10 Sep 2020 03:16:31

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:16:26', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a6040b4b-c727-4580-a976-98add8885a3f' User entered '09 Sep 2020 22:16'	System	10 Sep 2020 03:16:31
	System	10 Sep 2020 03:16:31

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:00:12', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1e2ffd19-4a25-403b-9098-8908a45420fb'	System	03 Sep 2020 20:01:24
User entered 'None (1)'	System	03 Sep 2020 20:01:24

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:00:19', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1e2ffd19-4a25-403b-9098-8908a45420fb'	System	03 Sep 2020 20:01:24
User entered 'No (N)'	System	03 Sep 2020 20:01:24

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:00:25', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1e2ffd19-4a25-403b-9098-8908a45420fb'	System	03 Sep 2020 20:01:24
User entered 'No (N)'	System	03 Sep 2020 20:01:24

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:14', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1e2ffd19-4a25-403b-9098-8908a45420fb'	System	03 Sep 2020 20:01:24
User entered 'None (1)'	System	03 Sep 2020 20:01:24

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:19', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1e2ffd19-4a25-403b-9098-8908a45420fb'	System	03 Sep 2020 20:01:24
User entered '03 Sep 2020 15:01'	System	03 Sep 2020 20:01:24

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '03 Sep 2020 14:50'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '03 Sep 2020 17:20'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:22:17', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8427cca8-2f99-4f74-b14b-42807127d473'	System	04 Sep 2020 02:22:42
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 02:22:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:22:15', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8427cca8-2f99-4f74-b14b-42807127d473'	System	04 Sep 2020 02:22:42
User entered 'No (N)'	System	04 Sep 2020 02:22:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:22:14', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8427cca8-2f99-4f74-b14b-42807127d473'	System	04 Sep 2020 02:22:42
User entered 'No (N)'	System	04 Sep 2020 02:22:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:22:12', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8427cca8-2f99-4f74-b14b-42807127d473'	System	04 Sep 2020 02:22:42
User entered 'None (1)'	System	04 Sep 2020 02:22:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:22:39', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8427cca8-2f99-4f74-b14b-42807127d473'	System	04 Sep 2020 02:22:42
User entered '03 Sep 2020 21:22'	System	04 Sep 2020 02:22:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '03 Sep 2020 18:15'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 2'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:38:35', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dc89fb26-88db-47cb-b7d8-9b5c18150573'	System	05 Sep 2020 02:39:09
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 02:39:09

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:38:12', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dc89fb26-88db-47cb-b7d8-9b5c18150573'	System	05 Sep 2020 02:39:09
User entered 'No (N)'	System	05 Sep 2020 02:39:09

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:38:11', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dc89fb26-88db-47cb-b7d8-9b5c18150573'	System	05 Sep 2020 02:39:09
User entered 'No (N)'	System	05 Sep 2020 02:39:09

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:38:52', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dc89fb26-88db-47cb-b7d8-9b5c18150573'	System	05 Sep 2020 02:39:09
User entered 'None (1)'	System	05 Sep 2020 02:39:09

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:39:05', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dc89fb26-88db-47cb-b7d8-9b5c18150573'	System	05 Sep 2020 02:39:09
User entered '04 Sep 2020 21:39'	System	05 Sep 2020 02:39:09

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 3'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:27:48', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2d256a49-b912-4df3-ba7a-1ab8e63f4b27'	System	06 Sep 2020 02:28:37
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 02:28:37

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:27:57', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2d256a49-b912-4df3-ba7a-1ab8e63f4b27'	System	06 Sep 2020 02:28:37
User entered 'No (N)'	System	06 Sep 2020 02:28:37

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:28:12', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2d256a49-b912-4df3-ba7a-1ab8e63f4b27'	System	06 Sep 2020 02:28:37
User entered 'No (N)'	System	06 Sep 2020 02:28:37

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:28:23', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2d256a49-b912-4df3-ba7a-1ab8e63f4b27'	System	06 Sep 2020 02:28:37
User entered 'None (1)'	System	06 Sep 2020 02:28:37

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:28:32', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2d256a49-b912-4df3-ba7a-1ab8e63f4b27'	System	06 Sep 2020 02:28:37
User entered '05 Sep 2020 21:28'	System	06 Sep 2020 02:28:37

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 4'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:02', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8cd14d1f-9b57-4017-bc86-ec06c9ee279f'	System	07 Sep 2020 05:13:26
User entered 'None (1)'	System	07 Sep 2020 05:13:26

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:06', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8cd14d1f-9b57-4017-bc86-ec06c9ee279f'	System	07 Sep 2020 05:13:26
User entered 'No (N)'	System	07 Sep 2020 05:13:26

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:08', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8cd14d1f-9b57-4017-bc86-ec06c9ee279f'	System	07 Sep 2020 05:13:26
User entered 'No (N)'	System	07 Sep 2020 05:13:26

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:11', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8cd14d1f-9b57-4017-bc86-ec06c9ee279f'	System	07 Sep 2020 05:13:26
User entered 'None (1)'	System	07 Sep 2020 05:13:26

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:18', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8cd14d1f-9b57-4017-bc86-ec06c9ee279f'	System	07 Sep 2020 05:13:26
User entered '07 Sep 2020 00:13'	System	07 Sep 2020 05:13:26

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 5'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:13', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '11c49c25-d625-4cd9-83be-7abb2cfd3b90'	System	08 Sep 2020 03:16:42
User entered 'None (1)'	System	08 Sep 2020 03:16:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:17', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '11c49c25-d625-4cd9-83be-7abb2cfd3b90'	System	08 Sep 2020 03:16:42
User entered 'No (N)'	System	08 Sep 2020 03:16:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:20', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '11c49c25-d625-4cd9-83be-7abb2cfd3b90'	System	08 Sep 2020 03:16:42
User entered 'No (N)'	System	08 Sep 2020 03:16:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:24', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '11c49c25-d625-4cd9-83be-7abb2cfd3b90'	System	08 Sep 2020 03:16:42
User entered 'None (1)'	System	08 Sep 2020 03:16:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:36', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '11c49c25-d625-4cd9-83be-7abb2cfd3b90'	System	08 Sep 2020 03:16:42
User entered '07 Sep 2020 22:16'	System	08 Sep 2020 03:16:42

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 6'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:03:46', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b3a09134-107c-47bd-b3e2-65105b13c172'	System	09 Sep 2020 03:04:21
User entered 'None (1)'	System	09 Sep 2020 03:04:21

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:03:51', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b3a09134-107c-47bd-b3e2-65105b13c172'	System	09 Sep 2020 03:04:21
User entered 'No (N)'	System	09 Sep 2020 03:04:21

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:03:57', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b3a09134-107c-47bd-b3e2-65105b13c172'	System	09 Sep 2020 03:04:21
User entered 'No (N)'	System	09 Sep 2020 03:04:21

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:06', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b3a09134-107c-47bd-b3e2-65105b13c172'	System	09 Sep 2020 03:04:21
User entered 'None (1)'	System	09 Sep 2020 03:04:21

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:14', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b3a09134-107c-47bd-b3e2-65105b13c172'	System	09 Sep 2020 03:04:21
User entered '08 Sep 2020 22:04'	System	09 Sep 2020 03:04:21

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 7'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:16:33', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2cb5d81c-3ead-4592-8e9f-d0cbcd1758b2'	System	10 Sep 2020 03:17:05
User entered 'None (1)'	System	10 Sep 2020 03:17:05

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:16:37', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2cb5d81c-3ead-4592-8e9f-d0cbcd1758b2'	System	10 Sep 2020 03:17:05
User entered 'No (N)'	System	10 Sep 2020 03:17:05

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:16:43', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2cb5d81c-3ead-4592-8e9f-d0cbcd1758b2'	System	10 Sep 2020 03:17:05
User entered 'No (N)'	System	10 Sep 2020 03:17:05

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:16:47', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2cb5d81c-3ead-4592-8e9f-d0cbcd1758b2'	System	10 Sep 2020 03:17:05
User entered 'None (1)'	System	10 Sep 2020 03:17:05

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:16:57', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2cb5d81c-3ead-4592-8e9f-d0cbcd1758b2'	System	10 Sep 2020 03:17:05
User entered '09 Sep 2020 22:16'	System	10 Sep 2020 03:17:05

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:27', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '94bef6c3-5987-456a-9ef7-0d30af0c55bc'	System	03 Sep 2020 20:01:53
User entered 'None (0)'	System	03 Sep 2020 20:01:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:30', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '94bef6c3-5987-456a-9ef7-0d30af0c55bc'	System	03 Sep 2020 20:01:53
User entered 'None (0)'	System	03 Sep 2020 20:01:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:33', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '94bef6c3-5987-456a-9ef7-0d30af0c55bc'	System	03 Sep 2020 20:01:53
User entered 'None (0)'	System	03 Sep 2020 20:01:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:35', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '94bef6c3-5987-456a-9ef7-0d30af0c55bc'	System	03 Sep 2020 20:01:53
User entered 'None (0)'	System	03 Sep 2020 20:01:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:38', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '94bef6c3-5987-456a-9ef7-0d30af0c55bc'	System	03 Sep 2020 20:01:53
User entered 'None (0)'	System	03 Sep 2020 20:01:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:40', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '94bef6c3-5987-456a-9ef7-0d30af0c55bc'	System	03 Sep 2020 20:01:53
User entered 'None (0)'	System	03 Sep 2020 20:01:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:45', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '94bef6c3-5987-456a-9ef7-0d30af0c55bc'	System	03 Sep 2020 20:01:53
User entered 'No (N)'	System	03 Sep 2020 20:01:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T15:01:49', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '94bef6c3-5987-456a-9ef7-0d30af0c55bc'	System	03 Sep 2020 20:01:53
User entered '03 Sep 2020 15:01'	System	03 Sep 2020 20:01:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '03 Sep 2020 14:50'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '03 Sep 2020 17:20'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:22:48', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1a1275e3-aaea-48b9-9801-eba78dddaed8'	System	04 Sep 2020 02:23:25
User entered 'None (0)'	System	04 Sep 2020 02:23:25

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:23:02', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1a1275e3-aaea-48b9-9801-eba78dddaed8'	System	04 Sep 2020 02:23:25
User entered 'None (0)'	System	04 Sep 2020 02:23:25

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:23:05', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1a1275e3-aaea-48b9-9801-eba78dddaed8'	System	04 Sep 2020 02:23:25
User entered 'None (0)'	System	04 Sep 2020 02:23:25

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:23:07', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1a1275e3-aaea-48b9-9801-eba78dddaed8'	System	04 Sep 2020 02:23:25
User entered 'None (0)'	System	04 Sep 2020 02:23:25

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:23:09', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1a1275e3-aaea-48b9-9801-eba78dddaed8'	System	04 Sep 2020 02:23:25
User entered 'None (0)'	System	04 Sep 2020 02:23:25

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:23:11', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1a1275e3-aaea-48b9-9801-eba78dddaed8'	System	04 Sep 2020 02:23:25
User entered 'None (0)'	System	04 Sep 2020 02:23:25

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:23:16', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1a1275e3-aaea-48b9-9801-eba78dddaed8'	System	04 Sep 2020 02:23:25
User entered 'No (N)'	System	04 Sep 2020 02:23:25

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-03T21:23:23', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1a1275e3-aaea-48b9-9801-eba78dddaed8'	System	04 Sep 2020 02:23:25
User entered '03 Sep 2020 21:23'	System	04 Sep 2020 02:23:25

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '03 Sep 2020 18:15'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 2'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:39:41', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9a933ace-7f98-4272-a445-f8ef643978e4'	System	05 Sep 2020 02:40:34
User entered 'None (0)'	System	05 Sep 2020 02:40:34

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:39:45', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9a933ace-7f98-4272-a445-f8ef643978e4'	System	05 Sep 2020 02:40:34
User entered 'None (0)'	System	05 Sep 2020 02:40:34

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:39:48', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9a933ace-7f98-4272-a445-f8ef643978e4'	System	05 Sep 2020 02:40:34
User entered 'None (0)'	System	05 Sep 2020 02:40:34

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:39:56', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9a933ace-7f98-4272-a445-f8ef643978e4'	System	05 Sep 2020 02:40:34
User entered 'None (0)'	System	05 Sep 2020 02:40:34

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:39:59', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9a933ace-7f98-4272-a445-f8ef643978e4'	System	05 Sep 2020 02:40:34
User entered 'None (0)'	System	05 Sep 2020 02:40:34

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:40:01', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9a933ace-7f98-4272-a445-f8ef643978e4'	System	05 Sep 2020 02:40:34
User entered 'None (0)'	System	05 Sep 2020 02:40:34

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:40:05', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9a933ace-7f98-4272-a445-f8ef643978e4'	System	05 Sep 2020 02:40:34
User entered 'No (N)'	System	05 Sep 2020 02:40:34

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-04T21:40:30', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9a933ace-7f98-4272-a445-f8ef643978e4'	System	05 Sep 2020 02:40:34
User entered '04 Sep 2020 21:40'	System	05 Sep 2020 02:40:34

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 3'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:28:38', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ff2a870e-ca01-4668-99f0-0fbcebb46112'	System	06 Sep 2020 02:29:12
User entered 'None (0)'	System	06 Sep 2020 02:29:12

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:28:43', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ff2a870e-ca01-4668-99f0-0fbcebb46112'	System	06 Sep 2020 02:29:12
User entered 'None (0)'	System	06 Sep 2020 02:29:12

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:28:46', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ff2a870e-ca01-4668-99f0-0fbcebb46112'	System	06 Sep 2020 02:29:12
User entered 'None (0)'	System	06 Sep 2020 02:29:12

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:28:49', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ff2a870e-ca01-4668-99f0-0fbcebb46112'	System	06 Sep 2020 02:29:12
User entered 'None (0)'	System	06 Sep 2020 02:29:12

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:28:52', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ff2a870e-ca01-4668-99f0-0fbcebb46112'	System	06 Sep 2020 02:29:12
User entered 'None (0)'	System	06 Sep 2020 02:29:12

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:28:55', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ff2a870e-ca01-4668-99f0-0fbcebb46112'	System	06 Sep 2020 02:29:12
User entered 'None (0)'	System	06 Sep 2020 02:29:12

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:29:02', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ff2a870e-ca01-4668-99f0-0fbcebb46112'	System	06 Sep 2020 02:29:12
User entered 'No (N)'	System	06 Sep 2020 02:29:12

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-05T21:29:08', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ff2a870e-ca01-4668-99f0-0fbcebb46112'	System	06 Sep 2020 02:29:12
User entered '05 Sep 2020 21:29'	System	06 Sep 2020 02:29:12

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 4'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:23', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '703fa691-e2f1-4994-9e1b-b6d5ff403639'	System	07 Sep 2020 05:13:50
User entered 'None (0)'	System	07 Sep 2020 05:13:50

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:25', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '703fa691-e2f1-4994-9e1b-b6d5ff403639'	System	07 Sep 2020 05:13:50
User entered 'None (0)'	System	07 Sep 2020 05:13:50

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:27', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '703fa691-e2f1-4994-9e1b-b6d5ff403639'	System	07 Sep 2020 05:13:50
User entered 'None (0)'	System	07 Sep 2020 05:13:50

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:30', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '703fa691-e2f1-4994-9e1b-b6d5ff403639'	System	07 Sep 2020 05:13:50
User entered 'None (0)'	System	07 Sep 2020 05:13:50

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:32', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '703fa691-e2f1-4994-9e1b-b6d5ff403639'	System	07 Sep 2020 05:13:50
User entered 'None (0)'	System	07 Sep 2020 05:13:50

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:34', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '703fa691-e2f1-4994-9e1b-b6d5ff403639'	System	07 Sep 2020 05:13:50
User entered 'None (0)'	System	07 Sep 2020 05:13:50

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:39', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '703fa691-e2f1-4994-9e1b-b6d5ff403639'	System	07 Sep 2020 05:13:50
User entered 'No (N)'	System	07 Sep 2020 05:13:50

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T00:13:45', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '703fa691-e2f1-4994-9e1b-b6d5ff403639'	System	07 Sep 2020 05:13:50
User entered '07 Sep 2020 00:13'	System	07 Sep 2020 05:13:50

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 5'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:41', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'acc48ff3-c60f-4263-886d-b07657b9506b'	System	08 Sep 2020 03:17:09
User entered 'None (0)'	System	08 Sep 2020 03:17:09

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:43', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'acc48ff3-c60f-4263-886d-b07657b9506b'	System	08 Sep 2020 03:17:09
User entered 'None (0)'	System	08 Sep 2020 03:17:09

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:47', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'acc48ff3-c60f-4263-886d-b07657b9506b'	System	08 Sep 2020 03:17:09
User entered 'None (0)'	System	08 Sep 2020 03:17:09

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:51', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'acc48ff3-c60f-4263-886d-b07657b9506b'	System	08 Sep 2020 03:17:09
User entered 'None (0)'	System	08 Sep 2020 03:17:09

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:55', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'acc48ff3-c60f-4263-886d-b07657b9506b'	System	08 Sep 2020 03:17:09
User entered 'None (0)'	System	08 Sep 2020 03:17:09

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:16:57', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'acc48ff3-c60f-4263-886d-b07657b9506b'	System	08 Sep 2020 03:17:09
User entered 'None (0)'	System	08 Sep 2020 03:17:09

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:17:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'acc48ff3-c60f-4263-886d-b07657b9506b'	System	08 Sep 2020 03:17:09
User entered 'No (N)'	System	08 Sep 2020 03:17:09

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-07T22:17:05', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'acc48ff3-c60f-4263-886d-b07657b9506b'	System	08 Sep 2020 03:17:09
User entered '07 Sep 2020 22:17'	System	08 Sep 2020 03:17:09

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 6'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:18', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2719826-8da1-45af-8f26-45207639bd08'	System	09 Sep 2020 03:05:03
User entered 'None (0)'	System	09 Sep 2020 03:05:03

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:21', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2719826-8da1-45af-8f26-45207639bd08'	System	09 Sep 2020 03:05:03
User entered 'None (0)'	System	09 Sep 2020 03:05:03

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:25', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2719826-8da1-45af-8f26-45207639bd08'	System	09 Sep 2020 03:05:03
User entered 'None (0)'	System	09 Sep 2020 03:05:03

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:28', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2719826-8da1-45af-8f26-45207639bd08'	System	09 Sep 2020 03:05:03
User entered 'None (0)'	System	09 Sep 2020 03:05:03

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:31', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2719826-8da1-45af-8f26-45207639bd08'	System	09 Sep 2020 03:05:03
User entered 'None (0)'	System	09 Sep 2020 03:05:03

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:33', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2719826-8da1-45af-8f26-45207639bd08'	System	09 Sep 2020 03:05:03
User entered 'None (0)'	System	09 Sep 2020 03:05:03

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:36', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2719826-8da1-45af-8f26-45207639bd08'	System	09 Sep 2020 03:05:03
User entered 'No (N)'	System	09 Sep 2020 03:05:03

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-08T22:04:56', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2719826-8da1-45af-8f26-45207639bd08'	System	09 Sep 2020 03:05:03
User entered '08 Sep 2020 22:04'	System	09 Sep 2020 03:05:03

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 7'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:17:04', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd3e14331-b3cb-4859-b9b4-b685c1f5f361'	System	10 Sep 2020 03:17:53
User entered 'None (0)'	System	10 Sep 2020 03:17:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:17:22', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd3e14331-b3cb-4859-b9b4-b685c1f5f361'	System	10 Sep 2020 03:17:53
User entered 'None (0)'	System	10 Sep 2020 03:17:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:17:25', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd3e14331-b3cb-4859-b9b4-b685c1f5f361'	System	10 Sep 2020 03:17:53
User entered 'None (0)'	System	10 Sep 2020 03:17:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:17:27', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd3e14331-b3cb-4859-b9b4-b685c1f5f361'	System	10 Sep 2020 03:17:53
User entered 'None (0)'	System	10 Sep 2020 03:17:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:17:30', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd3e14331-b3cb-4859-b9b4-b685c1f5f361'	System	10 Sep 2020 03:17:53
User entered 'None (0)'	System	10 Sep 2020 03:17:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:17:32', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd3e14331-b3cb-4859-b9b4-b685c1f5f361'	System	10 Sep 2020 03:17:53
User entered 'None (0)'	System	10 Sep 2020 03:17:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:17:42', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd3e14331-b3cb-4859-b9b4-b685c1f5f361'	System	10 Sep 2020 03:17:53
User entered 'No (N)'	System	10 Sep 2020 03:17:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-09-09T22:17:47', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd3e14331-b3cb-4859-b9b4-b685c1f5f361'	System	10 Sep 2020 03:17:53
User entered '09 Sep 2020 22:17'	System	10 Sep 2020 03:17:53

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:39:48

US3572125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:18:47
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:30:26

US3572125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '10 Sep 2020'	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:30:26

US3572125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:30:26

US3572125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:30:26

US3572125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:30:31

US3572125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'l'	System	18 Sep 2020 17:30:31

US3572125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:31:02

US3572125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '18 Sep 2020'	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:31:02

US3572125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:31:02

US3572125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:31:02

US3572125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	24 Sep 2020 16:25:40

US3572125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'l'	System	24 Sep 2020 16:25:40

US3572125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	24 Sep 2020 16:25:50

US3572125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '24 Sep 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	24 Sep 2020 16:25:50

US3572125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	24 Sep 2020 16:25:50

US3572125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	24 Sep 2020 16:25:50

US3572125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	24 Sep 2020 16:25:54

US3572125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'I'	System	24 Sep 2020 16:25:54

US3572125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06NOV2020 is reported underVisit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 15:41:30
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06NOV2020 is reported underVisit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Sample information added to EDC under V3D57' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 00:59:23
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06NOV2020 is reported underVisit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 04:36:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 01:17:59

US3572125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:17:59

US3572125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:17:59

US3572125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'VISIT2'	System	06 Oct 2020 01:17:59

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '13:10'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '02 Oct 2020 13:10'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '97.9' F	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Temporal'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '91'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'bpm'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '18'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'breaths/min'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '144'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '89'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '14:09'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '02 Oct 2020 14:09'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '97.5' F	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Temporal'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '80'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'bpm'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '18'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'breaths/min'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '119'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '75'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	06 Oct 2020 01:19:49

US3572125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:20:09

US3572125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:20:09

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '2 Oct 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '13:39'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '2 Oct 2020 13:39'	System	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'ONCE'	System	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:15:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 18:39:11

US3572125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:20:37

US3572125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:20:37

US3572125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '13:11'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:20:37

US3572125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '02 Oct 2020 13:11'	System	06 Oct 2020 01:20:37

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:21:00

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Oct 2020 01:21:00

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:21:00

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '13:04'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:21:00

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:15:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '02 Oct 2020 13:04'	System	06 Oct 2020 01:21:00

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:15:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Oct 2020 01:21:00

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:21:00

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:15:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:21:00

US3572125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered empty.	System	06 Oct 2020 01:21:00

US3572125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:21:07

US3572125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'I'	System	06 Oct 2020 01:21:07

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:06:43', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c7c6b501-3979-4189-b8a3-1bc0efe4ba68'	System	02 Oct 2020 19:07:06
User entered 'Yes (Y)'	System	02 Oct 2020 19:07:06

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:06:49', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c7c6b501-3979-4189-b8a3-1bc0efe4ba68'	System	02 Oct 2020 19:07:06
User entered '97.5'	System	02 Oct 2020 19:07:06

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:06:54', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c7c6b501-3979-4189-b8a3-1bc0efe4ba68'	System	02 Oct 2020 19:07:06
User entered 'No (N)'	System	02 Oct 2020 19:07:06

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:07:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c7c6b501-3979-4189-b8a3-1bc0efe4ba68'	System	02 Oct 2020 19:07:06
User entered '02 Oct 2020 14:07'	System	02 Oct 2020 19:07:06

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '02 Oct 2020 13:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '02 Oct 2020 16:29'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:53:01', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '91bf69bf-775e-4ab4-89bb-47fc03428cf4'	System	03 Oct 2020 02:53:26
User entered 'Yes (Y)'	System	03 Oct 2020 02:53:26

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:53:09', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '91bf69bf-775e-4ab4-89bb-47fc03428cf4' User entered '98.4'	System	03 Oct 2020 02:53:26
	System	03 Oct 2020 02:53:26

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:53:14', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '91bf69bf-775e-4ab4-89bb-47fc03428cf4'	System	03 Oct 2020 02:53:26
User entered 'No (N)'	System	03 Oct 2020 02:53:26

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:53:20', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '91bf69bf-775e-4ab4-89bb-47fc03428cf4'	System	03 Oct 2020 02:53:26
User entered '02 Oct 2020 21:53'	System	03 Oct 2020 02:53:26

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '02 Oct 2020 17:24'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 2'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T20:56:29', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '10081dea-385d-4c52-960f-11e2c24fceb4'	System	04 Oct 2020 01:57:19
User entered 'Yes (Y)'	System	04 Oct 2020 01:57:19

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T20:56:38', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '10081dea-385d-4c52-960f-11e2c24fceb4' User entered '100.2'	System	04 Oct 2020 01:57:19
	System	04 Oct 2020 01:57:19

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T20:56:42', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '10081dea-385d-4c52-960f-11e2c24fceb4'	System	04 Oct 2020 01:57:19
User entered 'Yes (Y)'	System	04 Oct 2020 01:57:19

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
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 'aspirin 650 mg for fever' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 12:19:00
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T20:56:56', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '10081dea-385d-4c52-960f-11e2c24fceb4'	Jackie Ziegler (b) (4) (b) (4)	09 Oct 2020 18:44:16
User entered '1'	System	04 Oct 2020 01:57:19
	System	04 Oct 2020 01:57:19
	System	04 Oct 2020 01:57:19

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
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 'aspirin 650 mg for fever' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 12:19:03
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T20:56:56', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '10081dea-385d-4c52-960f-11e2c24fceb4'	Jackie Ziegler (b) (4) (b) (4)	09 Oct 2020 18:44:21
User entered '1'	System	04 Oct 2020 01:57:19
	System	04 Oct 2020 01:57:19
	System	04 Oct 2020 01:57:19

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T20:57:12', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '10081dea-385d-4c52-960f-11e2c24fceb4'	System	04 Oct 2020 01:57:19
User entered '03 Oct 2020 20:57'	System	04 Oct 2020 01:57:19

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 3'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:01:19', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bc298e7c-a281-4f70-a33f-6d0e895b97bd'	System	05 Oct 2020 03:02:17
User entered 'Yes (Y)'	System	05 Oct 2020 03:02:17

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:01:24', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bc298e7c-a281-4f70-a33f-6d0e895b97bd'	System	05 Oct 2020 03:02:17
User entered '99.3'	System	05 Oct 2020 03:02:17

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:01:47', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bc298e7c-a281-4f70-a33f-6d0e895b97bd'	System	05 Oct 2020 03:02:17
User entered 'Yes (Y)'	System	05 Oct 2020 03:02:17

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:02:09', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bc298e7c-a281-4f70-a33f-6d0e895b97bd'	System	05 Oct 2020 03:02:17
User entered '0'	System	05 Oct 2020 03:02:17

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
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 'aspirin 650 mg for fever' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 12:19:09
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:02:09', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bc298e7c-a281-4f70-a33f-6d0e895b97bd'	Jackie Ziegler (b) (4) (b) (4)	09 Oct 2020 18:44:29
User entered '1'	System	05 Oct 2020 03:02:17
	System	05 Oct 2020 03:02:17
	System	05 Oct 2020 03:02:17

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:02:12', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bc298e7c-a281-4f70-a33f-6d0e895b97bd'	System	05 Oct 2020 03:02:17
User entered '04 Oct 2020 22:02'	System	05 Oct 2020 03:02:17

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 4'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:38:31', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bfe35a25-37a1-4228-9b91-d4c08c5ce352'	System	06 Oct 2020 02:39:11
User entered 'Yes (Y)'	System	06 Oct 2020 02:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:38:49', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bfe35a25-37a1-4228-9b91-d4c08c5ce352'	System	06 Oct 2020 02:39:11
User entered '98.6'	System	06 Oct 2020 02:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:38:52', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bfe35a25-37a1-4228-9b91-d4c08c5ce352'	System	06 Oct 2020 02:39:11
User entered 'No (N)'	System	06 Oct 2020 02:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:39:04', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'bfe35a25-37a1-4228-9b91-d4c08c5ce352'	System	06 Oct 2020 02:39:11
User entered '05 Oct 2020 21:39'	System	06 Oct 2020 02:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 5'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:11:32', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2b64907c-e44f-4fa9-badd-46b1c3e4f4fc'	System	07 Oct 2020 02:11:55
User entered 'Yes (Y)'	System	07 Oct 2020 02:11:55

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:11:40', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2b64907c-e44f-4fa9-badd-46b1c3e4f4fc'	System	07 Oct 2020 02:11:55
User entered '98.6'	System	07 Oct 2020 02:11:55

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:11:43', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2b64907c-e44f-4fa9-badd-46b1c3e4f4fc'	System	07 Oct 2020 02:11:55
User entered 'No (N)'	System	07 Oct 2020 02:11:55

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:11:52', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2b64907c-e44f-4fa9-badd-46b1c3e4f4fc'	System	07 Oct 2020 02:11:55
User entered '06 Oct 2020 21:11'	System	07 Oct 2020 02:11:55

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 6'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:33:48', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '688b53c1-fa42-429c-a6fd-4672c4b0db15'	System	08 Oct 2020 03:34:06
User entered 'Yes (Y)'	System	08 Oct 2020 03:34:06

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:33:53', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '688b53c1-fa42-429c-a6fd-4672c4b0db15'	System	08 Oct 2020 03:34:06
User entered '98.7'	System	08 Oct 2020 03:34:06

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:33:55', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '688b53c1-fa42-429c-a6fd-4672c4b0db15'	System	08 Oct 2020 03:34:06
User entered 'No (N)'	System	08 Oct 2020 03:34:06

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:02', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '688b53c1-fa42-429c-a6fd-4672c4b0db15'	System	08 Oct 2020 03:34:06
User entered '07 Oct 2020 22:34'	System	08 Oct 2020 03:34:06

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 7'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:55:37', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '308401fa-cb2b-4592-9e5a-18399359502e'	System	09 Oct 2020 03:55:55
User entered 'Yes (Y)'	System	09 Oct 2020 03:55:55

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:55:42', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '308401fa-cb2b-4592-9e5a-18399359502e' User entered '99.2'	System	09 Oct 2020 03:55:55
	System	09 Oct 2020 03:55:55

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:55:45', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '308401fa-cb2b-4592-9e5a-18399359502e'	System	09 Oct 2020 03:55:55
User entered 'No (N)'	System	09 Oct 2020 03:55:55

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:55:49', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '308401fa-cb2b-4592-9e5a-18399359502e' User entered '08 Oct 2020 22:55'	System	09 Oct 2020 03:55:55
	System	09 Oct 2020 03:55:55

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:07:13', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5e47fe98-7e45-4f78-b13b-66cf5d492214'	System	02 Oct 2020 19:07:58
User entered 'None (1)'	System	02 Oct 2020 19:07:58

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:07:36', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5e47fe98-7e45-4f78-b13b-66cf5d492214'	System	02 Oct 2020 19:07:58
User entered 'No (N)'	System	02 Oct 2020 19:07:58

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:07:42', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5e47fe98-7e45-4f78-b13b-66cf5d492214'	System	02 Oct 2020 19:07:58
User entered 'No (N)'	System	02 Oct 2020 19:07:58

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:07:46', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5e47fe98-7e45-4f78-b13b-66cf5d492214'	System	02 Oct 2020 19:07:58
User entered 'None (1)'	System	02 Oct 2020 19:07:58

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:07:52', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5e47fe98-7e45-4f78-b13b-66cf5d492214' User entered '02 Oct 2020 14:07'	System	02 Oct 2020 19:07:58
	System	02 Oct 2020 19:07:58

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '02 Oct 2020 13:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '02 Oct 2020 16:29'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:53:55', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f2dd907a-da53-4f41-b02b-55c821f5d67d'	System	03 Oct 2020 02:54:45
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 02:54:45

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:53:53', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f2dd907a-da53-4f41-b02b-55c821f5d67d'	System	03 Oct 2020 02:54:45
User entered 'No (N)'	System	03 Oct 2020 02:54:45

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:53:52', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f2dd907a-da53-4f41-b02b-55c821f5d67d'	System	03 Oct 2020 02:54:45
User entered 'No (N)'	System	03 Oct 2020 02:54:45

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:53:59', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f2dd907a-da53-4f41-b02b-55c821f5d67d'	System	03 Oct 2020 02:54:45
User entered 'None (1)'	System	03 Oct 2020 02:54:45

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:54:41', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f2dd907a-da53-4f41-b02b-55c821f5d67d'	System	03 Oct 2020 02:54:45
User entered '02 Oct 2020 21:54'	System	03 Oct 2020 02:54:45

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '02 Oct 2020 17:24'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 2'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:02:28', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a0452a01-89be-4068-86d8-f8f933026ac2'	System	04 Oct 2020 02:04:00
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Oct 2020 02:04:00

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:03:35', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a0452a01-89be-4068-86d8-f8f933026ac2'	System	04 Oct 2020 02:04:00
User entered 'No (N)'	System	04 Oct 2020 02:04:00

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:03:40', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a0452a01-89be-4068-86d8-f8f933026ac2'	System	04 Oct 2020 02:04:00
User entered 'No (N)'	System	04 Oct 2020 02:04:00

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:03:46', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a0452a01-89be-4068-86d8-f8f933026ac2'	System	04 Oct 2020 02:04:00
User entered 'None (1)'	System	04 Oct 2020 02:04:00

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:03:54', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a0452a01-89be-4068-86d8-f8f933026ac2'	System	04 Oct 2020 02:04:00
User entered '03 Oct 2020 21:03'	System	04 Oct 2020 02:04:00

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 3'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:03:20', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd83a2576-e2c4-4985-96d3-53b389772e66'	System	05 Oct 2020 03:03:31
User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 03:03:31

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:03:17', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd83a2576-e2c4-4985-96d3-53b389772e66'	System	05 Oct 2020 03:03:31
User entered 'No (N)'	System	05 Oct 2020 03:03:31

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:03:16', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd83a2576-e2c4-4985-96d3-53b389772e66'	System	05 Oct 2020 03:03:31
User entered 'No (N)'	System	05 Oct 2020 03:03:31

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:03:23', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd83a2576-e2c4-4985-96d3-53b389772e66'	System	05 Oct 2020 03:03:31
User entered 'None (1)'	System	05 Oct 2020 03:03:31

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:03:26', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd83a2576-e2c4-4985-96d3-53b389772e66'	System	05 Oct 2020 03:03:31
User entered '04 Oct 2020 22:03'	System	05 Oct 2020 03:03:31

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 4'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:39:47', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2ac658eb-a586-4def-b6e0-9e84bc747291'	System	06 Oct 2020 02:40:22
User entered 'None (1)'	System	06 Oct 2020 02:40:22

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:39:53', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2ac658eb-a586-4def-b6e0-9e84bc747291'	System	06 Oct 2020 02:40:22
User entered 'No (N)'	System	06 Oct 2020 02:40:22

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:39:58', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2ac658eb-a586-4def-b6e0-9e84bc747291'	System	06 Oct 2020 02:40:22
User entered 'No (N)'	System	06 Oct 2020 02:40:22

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:40:07', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2ac658eb-a586-4def-b6e0-9e84bc747291'	System	06 Oct 2020 02:40:22
User entered 'None (1)'	System	06 Oct 2020 02:40:22

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:40:18', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2ac658eb-a586-4def-b6e0-9e84bc747291'	System	06 Oct 2020 02:40:22
User entered '05 Oct 2020 21:40'	System	06 Oct 2020 02:40:22

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 5'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c87ccb77-717c-4a31-becf-42aa92065c02'	System	07 Oct 2020 02:12:36
User entered 'None (1)'	System	07 Oct 2020 02:12:36

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:10', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c87ccb77-717c-4a31-becf-42aa92065c02'	System	07 Oct 2020 02:12:36
User entered 'No (N)'	System	07 Oct 2020 02:12:36

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:17', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c87ccb77-717c-4a31-becf-42aa92065c02'	System	07 Oct 2020 02:12:36
User entered 'No (N)'	System	07 Oct 2020 02:12:36

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:19', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c87ccb77-717c-4a31-becf-42aa92065c02'	System	07 Oct 2020 02:12:36
User entered 'None (1)'	System	07 Oct 2020 02:12:36

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:31', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c87ccb77-717c-4a31-becf-42aa92065c02'	System	07 Oct 2020 02:12:36
User entered '06 Oct 2020 21:12'	System	07 Oct 2020 02:12:36

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 6'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:06', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b69ea67a-0392-4253-92c1-2610ea8ef4b4'	System	08 Oct 2020 03:34:21
User entered 'None (1)'	System	08 Oct 2020 03:34:21

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:08', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b69ea67a-0392-4253-92c1-2610ea8ef4b4'	System	08 Oct 2020 03:34:21
User entered 'No (N)'	System	08 Oct 2020 03:34:21

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:11', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b69ea67a-0392-4253-92c1-2610ea8ef4b4'	System	08 Oct 2020 03:34:21
User entered 'No (N)'	System	08 Oct 2020 03:34:21

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:13', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b69ea67a-0392-4253-92c1-2610ea8ef4b4'	System	08 Oct 2020 03:34:21
User entered 'None (1)'	System	08 Oct 2020 03:34:21

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:18', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b69ea67a-0392-4253-92c1-2610ea8ef4b4'	System	08 Oct 2020 03:34:21
User entered '07 Oct 2020 22:34'	System	08 Oct 2020 03:34:21

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 7'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:55:53', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '6e6d89f3-3d72-4321-a565-95927dd35b75'	System	09 Oct 2020 03:56:16
User entered 'None (1)'	System	09 Oct 2020 03:56:16

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:55:56', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '6e6d89f3-3d72-4321-a565-95927dd35b75'	System	09 Oct 2020 03:56:16
User entered 'No (N)'	System	09 Oct 2020 03:56:16

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:55:59', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '6e6d89f3-3d72-4321-a565-95927dd35b75'	System	09 Oct 2020 03:56:16
User entered 'No (N)'	System	09 Oct 2020 03:56:16

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:56:02', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '6e6d89f3-3d72-4321-a565-95927dd35b75'	System	09 Oct 2020 03:56:16
User entered 'None (1)'	System	09 Oct 2020 03:56:16

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:56:13', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '6e6d89f3-3d72-4321-a565-95927dd35b75'	System	09 Oct 2020 03:56:16
User entered '08 Oct 2020 22:56'	System	09 Oct 2020 03:56:16

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:08:03', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dcc2e719-48cb-49f0-aa8a-ebe22dc0de13'	System	02 Oct 2020 19:08:32
User entered 'None (0)'	System	02 Oct 2020 19:08:32

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:08:08', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dcc2e719-48cb-49f0-aa8a-ebe22dc0de13'	System	02 Oct 2020 19:08:32
User entered 'None (0)'	System	02 Oct 2020 19:08:32

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:08:11', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dcc2e719-48cb-49f0-aa8a-ebe22dc0de13'	System	02 Oct 2020 19:08:32
User entered 'None (0)'	System	02 Oct 2020 19:08:32

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:08:13', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dcc2e719-48cb-49f0-aa8a-ebe22dc0de13'	System	02 Oct 2020 19:08:32
User entered 'None (0)'	System	02 Oct 2020 19:08:32

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:08:15', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dcc2e719-48cb-49f0-aa8a-ebe22dc0de13'	System	02 Oct 2020 19:08:32
User entered 'None (0)'	System	02 Oct 2020 19:08:32

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:08:17', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dcc2e719-48cb-49f0-aa8a-ebe22dc0de13'	System	02 Oct 2020 19:08:32
User entered 'None (0)'	System	02 Oct 2020 19:08:32

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:08:22', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dcc2e719-48cb-49f0-aa8a-ebe22dc0de13'	System	02 Oct 2020 19:08:32
User entered 'No (N)'	System	02 Oct 2020 19:08:32

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T14:08:28', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'dcc2e719-48cb-49f0-aa8a-ebe22dc0de13'	System	02 Oct 2020 19:08:32
User entered '02 Oct 2020 14:08'	System	02 Oct 2020 19:08:32

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '02 Oct 2020 13:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '02 Oct 2020 16:29'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:54:53', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ccd2cc1e-ea04-446f-bb2c-7b845ef4ac67'	System	03 Oct 2020 02:55:31
User entered 'None (0)'	System	03 Oct 2020 02:55:31

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:54:59', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ccd2cc1e-ea04-446f-bb2c-7b845ef4ac67'	System	03 Oct 2020 02:55:31
User entered 'None (0)'	System	03 Oct 2020 02:55:31

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:55:01', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ccd2cc1e-ea04-446f-bb2c-7b845ef4ac67'	System	03 Oct 2020 02:55:31
User entered 'None (0)'	System	03 Oct 2020 02:55:31

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:55:04', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ccd2cc1e-ea04-446f-bb2c-7b845ef4ac67'	System	03 Oct 2020 02:55:31
User entered 'None (0)'	System	03 Oct 2020 02:55:31

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:55:06', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ccd2cc1e-ea04-446f-bb2c-7b845ef4ac67'	System	03 Oct 2020 02:55:31
User entered 'None (0)'	System	03 Oct 2020 02:55:31

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:55:08', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ccd2cc1e-ea04-446f-bb2c-7b845ef4ac67'	System	03 Oct 2020 02:55:31
User entered 'None (0)'	System	03 Oct 2020 02:55:31

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:55:13', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ccd2cc1e-ea04-446f-bb2c-7b845ef4ac67'	System	03 Oct 2020 02:55:31
User entered 'No (N)'	System	03 Oct 2020 02:55:31

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-02T21:55:19', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'ccd2cc1e-ea04-446f-bb2c-7b845ef4ac67'	System	03 Oct 2020 02:55:31
User entered '02 Oct 2020 21:55'	System	03 Oct 2020 02:55:31

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '02 Oct 2020 17:24'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 2'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:04:13', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'flabed28-8ea4-406f-b549-50904af47259'	System	04 Oct 2020 02:05:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Oct 2020 02:05:49

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:04:27', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'flabed28-8ea4-406f-b549-50904af47259'	System	04 Oct 2020 02:05:49
User entered 'Some interference with activity (2)'	System	04 Oct 2020 02:05:49

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:04:36', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'flabed28-8ea4-406f-b549-50904af47259'	System	04 Oct 2020 02:05:49
User entered 'Some interference with activity (2)'	System	04 Oct 2020 02:05:49

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:04:42', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'flabed28-8ea4-406f-b549-50904af47259'	System	04 Oct 2020 02:05:49
User entered 'Some interference with activity (2)'	System	04 Oct 2020 02:05:49

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:04:59', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'flabed28-8ea4-406f-b549-50904af47259'	System	04 Oct 2020 02:05:49
User entered 'None (0)'	System	04 Oct 2020 02:05:49

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:05:10', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'flabed28-8ea4-406f-b549-50904af47259'	System	04 Oct 2020 02:05:49
User entered 'Some interference with activity not requiring medical attention (2)'	System	04 Oct 2020 02:05:49

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:05:19', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'flabed28-8ea4-406f-b549-50904af47259'	System	04 Oct 2020 02:05:49
User entered 'No (N)'	System	04 Oct 2020 02:05:49

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-03T21:05:44', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'flabed28-8ea4-406f-b549-50904af47259'	System	04 Oct 2020 02:05:49
User entered '03 Oct 2020 21:05'	System	04 Oct 2020 02:05:49

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 3'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:03:53', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '3d47c019-0372-4276-a71d-7883318da3a7'	System	05 Oct 2020 03:04:36
User entered 'None (0)'	System	05 Oct 2020 03:04:36

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:04:07', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '3d47c019-0372-4276-a71d-7883318da3a7'	System	05 Oct 2020 03:04:36
User entered 'No interference with activity (1)'	System	05 Oct 2020 03:04:36

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:04:10', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '3d47c019-0372-4276-a71d-7883318da3a7'	System	05 Oct 2020 03:04:36
User entered 'None (0)'	System	05 Oct 2020 03:04:36

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:04:12', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '3d47c019-0372-4276-a71d-7883318da3a7'	System	05 Oct 2020 03:04:36
User entered 'None (0)'	System	05 Oct 2020 03:04:36

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:04:14', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '3d47c019-0372-4276-a71d-7883318da3a7'	System	05 Oct 2020 03:04:36
User entered 'None (0)'	System	05 Oct 2020 03:04:36

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:04:16', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '3d47c019-0372-4276-a71d-7883318da3a7'	System	05 Oct 2020 03:04:36
User entered 'None (0)'	System	05 Oct 2020 03:04:36

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:04:18', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '3d47c019-0372-4276-a71d-7883318da3a7'	System	05 Oct 2020 03:04:36
User entered 'No (N)'	System	05 Oct 2020 03:04:36

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-04T22:04:31', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '3d47c019-0372-4276-a71d-7883318da3a7'	System	05 Oct 2020 03:04:36
User entered '04 Oct 2020 22:04'	System	05 Oct 2020 03:04:36

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 4'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:40:24', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '265cfb23-2ec3-4fb4-99ac-3b95055d05b9'	System	06 Oct 2020 02:41:25
User entered 'None (0)'	System	06 Oct 2020 02:41:25

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:40:35', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '265cfb23-2ec3-4fb4-99ac-3b95055d05b9'	System	06 Oct 2020 02:41:25
User entered 'None (0)'	System	06 Oct 2020 02:41:25

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:40:38', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '265cfb23-2ec3-4fb4-99ac-3b95055d05b9'	System	06 Oct 2020 02:41:25
User entered 'None (0)'	System	06 Oct 2020 02:41:25

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:40:42', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '265cfb23-2ec3-4fb4-99ac-3b95055d05b9'	System	06 Oct 2020 02:41:25
User entered 'None (0)'	System	06 Oct 2020 02:41:25

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:40:46', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '265cfb23-2ec3-4fb4-99ac-3b95055d05b9'	System	06 Oct 2020 02:41:25
User entered 'None (0)'	System	06 Oct 2020 02:41:25

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:40:49', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '265cfb23-2ec3-4fb4-99ac-3b95055d05b9'	System	06 Oct 2020 02:41:25
User entered 'None (0)'	System	06 Oct 2020 02:41:25

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:40:52', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '265cfb23-2ec3-4fb4-99ac-3b95055d05b9'	System	06 Oct 2020 02:41:25
User entered 'No (N)'	System	06 Oct 2020 02:41:25

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-05T21:41:21', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '265cfb23-2ec3-4fb4-99ac-3b95055d05b9'	System	06 Oct 2020 02:41:25
User entered '05 Oct 2020 21:41'	System	06 Oct 2020 02:41:25

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 5'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:35', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'aca2c711-23d2-4d9e-9520-48084fa00fcf'	System	07 Oct 2020 02:13:09
User entered 'None (0)'	System	07 Oct 2020 02:13:09

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:39', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'aca2c711-23d2-4d9e-9520-48084fa00fcf'	System	07 Oct 2020 02:13:09
User entered 'None (0)'	System	07 Oct 2020 02:13:09

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:41', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'aca2c711-23d2-4d9e-9520-48084fa00fcf'	System	07 Oct 2020 02:13:09
User entered 'None (0)'	System	07 Oct 2020 02:13:09

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:45', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'aca2c711-23d2-4d9e-9520-48084fa00fcf'	System	07 Oct 2020 02:13:09
User entered 'None (0)'	System	07 Oct 2020 02:13:09

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:47', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'aca2c711-23d2-4d9e-9520-48084fa00fcf'	System	07 Oct 2020 02:13:09
User entered 'None (0)'	System	07 Oct 2020 02:13:09

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:49', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'aca2c711-23d2-4d9e-9520-48084fa00fcf'	System	07 Oct 2020 02:13:09
User entered 'None (0)'	System	07 Oct 2020 02:13:09

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:12:52', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'aca2c711-23d2-4d9e-9520-48084fa00fcf'	System	07 Oct 2020 02:13:09
User entered 'No (N)'	System	07 Oct 2020 02:13:09

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-06T21:13:06', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'aca2c711-23d2-4d9e-9520-48084fa00fcf'	System	07 Oct 2020 02:13:09
User entered '06 Oct 2020 21:13'	System	07 Oct 2020 02:13:09

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 6'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:22', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1665b92d-0ffc-4a04-9ca1-402c4e6aab20'	System	08 Oct 2020 03:34:50
User entered 'None (0)'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:28', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1665b92d-0ffc-4a04-9ca1-402c4e6aab20'	System	08 Oct 2020 03:34:50
User entered 'No interference with activity (1)'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:31', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1665b92d-0ffc-4a04-9ca1-402c4e6aab20'	System	08 Oct 2020 03:34:50
User entered 'None (0)'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:32', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1665b92d-0ffc-4a04-9ca1-402c4e6aab20'	System	08 Oct 2020 03:34:50
User entered 'None (0)'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:34', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1665b92d-0ffc-4a04-9ca1-402c4e6aab20'	System	08 Oct 2020 03:34:50
User entered 'None (0)'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:36', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1665b92d-0ffc-4a04-9ca1-402c4e6aab20'	System	08 Oct 2020 03:34:50
User entered 'None (0)'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:43', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1665b92d-0ffc-4a04-9ca1-402c4e6aab20'	System	08 Oct 2020 03:34:50
User entered 'No (N)'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-07T22:34:47', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '1665b92d-0ffc-4a04-9ca1-402c4e6aab20'	System	08 Oct 2020 03:34:50
User entered '07 Oct 2020 22:34'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	02 Oct 2020 18:39:11
User entered 'Day 7'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:56:17', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'da34ee02-71cc-43e6-b40b-2fc30d40128c'	System	09 Oct 2020 03:57:05
User entered 'None (0)'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:56:20', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'da34ee02-71cc-43e6-b40b-2fc30d40128c'	System	09 Oct 2020 03:57:05
User entered 'No interference with activity (1)'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:56:22', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'da34ee02-71cc-43e6-b40b-2fc30d40128c'	System	09 Oct 2020 03:57:05
User entered 'None (0)'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:56:24', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'da34ee02-71cc-43e6-b40b-2fc30d40128c'	System	09 Oct 2020 03:57:05
User entered 'None (0)'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:56:26', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'da34ee02-71cc-43e6-b40b-2fc30d40128c'	System	09 Oct 2020 03:57:05
User entered 'None (0)'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:56:28', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'da34ee02-71cc-43e6-b40b-2fc30d40128c'	System	09 Oct 2020 03:57:05
User entered 'None (0)'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:56:32', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'da34ee02-71cc-43e6-b40b-2fc30d40128c'	System	09 Oct 2020 03:57:05
User entered 'No (N)'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-08T22:57:01', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'da34ee02-71cc-43e6-b40b-2fc30d40128c'	System	09 Oct 2020 03:57:05
User entered '08 Oct 2020 22:57'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 18:39:11

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	08 Oct 2020 03:34:50
User entered 'Day 8'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-09T19:58:38', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c49a9355-8dcc-4a9a-9404-ca075d2c2097'	System	10 Oct 2020 00:58:46
User entered 'No interference with activity (1)'	System	10 Oct 2020 00:58:46

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-09T19:58:43', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c49a9355-8dcc-4a9a-9404-ca075d2c2097'	System	10 Oct 2020 00:58:46
User entered '09 Oct 2020 19:58'	System	10 Oct 2020 00:58:46

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	09 Oct 2020 03:57:05
User entered 'Day 9'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-10T20:52:14', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8d0781e3-7396-4828-8900-cc337e08cb03'	System	11 Oct 2020 01:52:24
User entered 'No interference with activity (1)'	System	11 Oct 2020 01:52:24

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-10T20:52:19', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8d0781e3-7396-4828-8900-cc337e08cb03'	System	11 Oct 2020 01:52:24
User entered '10 Oct 2020 20:52'	System	11 Oct 2020 01:52:24

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	10 Oct 2020 00:58:46
User entered 'Day 10'	System	10 Oct 2020 00:58:46

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-11T20:50:55', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a44679ce-72df-4834-a754-1e7c024ed276'	System	12 Oct 2020 01:51:05
User entered 'None (0)'	System	12 Oct 2020 01:51:05

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:15:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-11T20:50:58', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'a44679ce-72df-4834-a754-1e7c024ed276'	System	12 Oct 2020 01:51:05
User entered '11 Oct 2020 20:50'	System	12 Oct 2020 01:51:05

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 00:58:46

US3572125

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 00:58:46

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	08 Oct 2020 03:34:50
User entered 'Day 8'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-09T19:58:48', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '72e6ec3d-fbc2-4748-a52e-2c36e288374f'	System	10 Oct 2020 00:58:54
User entered 'No (N)'	System	10 Oct 2020 00:58:54

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-09T19:58:51', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '72e6ec3d-fbc2-4748-a52e-2c36e288374f' User entered '09 Oct 2020 19:58'	System	10 Oct 2020 00:58:54
	System	10 Oct 2020 00:58:54

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 03:34:50

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	09 Oct 2020 03:57:05
User entered 'Day 9'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-10T20:52:25', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'adb92f35-6c5b-4a23-b9f0-204a07d1695a'	System	11 Oct 2020 01:52:36
User entered 'No (N)'	System	11 Oct 2020 01:52:36

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-10T20:52:33', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'adb92f35-6c5b-4a23-b9f0-204a07d1695a'	System	11 Oct 2020 01:52:36
User entered '10 Oct 2020 20:52'	System	11 Oct 2020 01:52:36

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:57:05

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
Data entry locked.	System	10 Oct 2020 00:58:46
User entered 'Day 10'	System	10 Oct 2020 00:58:46

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-11T20:51:11', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b14f12a9-e8aa-4f2a-a6bb-604ec2bd59d0'	System	12 Oct 2020 01:51:22
User entered 'No (N)'	System	12 Oct 2020 01:51:22

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:15:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-10-11T20:51:19', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'b14f12a9-e8aa-4f2a-a6bb-604ec2bd59d0'	System	12 Oct 2020 01:51:22
User entered '11 Oct 2020 20:51'	System	12 Oct 2020 01:51:22

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:15:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '11 Oct 2020 12:00'	System	10 Oct 2020 00:58:46

US3572125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:15:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:19:00
User entered '12 Oct 2020 11:59'	System	10 Oct 2020 00:58:46

US3572125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 18:56:14

US3572125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '9 Oct 2020'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 18:56:14

US3572125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 18:56:14

US3572125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 18:56:14
	(b) (4)	

US3572125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 18:56:19

US3572125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'l'	System	09 Oct 2020 18:56:19

US3572125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	19 Oct 2020 21:28:54

US3572125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '19 Oct 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:28:54

US3572125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	19 Oct 2020 21:28:54

US3572125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:28:54

US3572125

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	19 Oct 2020 21:28:59

US3572125

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'l'	System	19 Oct 2020 21:28:59

US3572125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	24 Oct 2020 00:00:15

US3572125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '23 Oct 2020'	(b) (4) Jackie Ziegler (b) (4)	24 Oct 2020 00:00:15

US3572125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	24 Oct 2020 00:00:15

US3572125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	24 Oct 2020 00:00:15
	(b) (4)	

US3572125

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	24 Oct 2020 00:00:20

US3572125

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'l'	System	24 Oct 2020 00:00:20

US3572125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:15

US3572125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:15

US3572125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:15

US3572125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'VISIT3'	System	03 Dec 2020 17:45:15

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '10:40'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '6 Nov 2020 10:40'	System	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '86'	(b) (4) (u) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'bpm'	System	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '18'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'breaths/min'	System	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '142'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '94'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'mmHg'	System	03 Dec 2020 17:45:57

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59

US3572125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59

US3572125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:10

US3572125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:10

US3572125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:28

US3572125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:28

US3572125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User entered '10:50'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:46:28

US3572125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered '6 Nov 2020 10:50'	System	03 Dec 2020 17:46:28

US3572125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:12:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (u) (4), (b) (6)	14 Jan 2021 17:04:20
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'data entered' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 01:51:48
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 17:43:52
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	25 Nov 2020 01:30:30

US3572125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'I'	System	25 Nov 2020 01:30:30

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 64'	System	03 Sep 2020 19:39:48

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15
Data entry locked.	System	03 Sep 2020 19:39:48
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 19:39:48

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15
Data entry locked.	System	03 Sep 2020 19:39:48
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 71'	System	03 Sep 2020 19:39:48

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15
Data entry locked.	System	03 Sep 2020 19:39:48
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 19:39:48

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15
Data entry locked.	System	03 Sep 2020 19:39:48
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15
Data entry locked.	System	03 Sep 2020 19:39:48
User entered 'Day 78'	System	03 Sep 2020 19:39:48

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15
Data entry locked.	System	03 Sep 2020 19:39:48
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 19:39:48

US3572125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:26:15
Data entry locked.	System	03 Sep 2020 19:39:48
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 19:39:48

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-11-24T19:31:33', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2ad588e-19d5-4e9e-9ac1-5d8c70941499'	System	25 Nov 2020 01:31:52
User entered 'No (N)'	System	25 Nov 2020 01:31:52

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2020-11-24T19:31:37', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2ad588e-19d5-4e9e-9ac1-5d8c70941499'	System	25 Nov 2020 01:31:52
User entered 'No (N)'	System	25 Nov 2020 01:31:52

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-11-24T19:31:47', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd2ad588e-19d5-4e9e-9ac1-5d8c70941499'	System	25 Nov 2020 01:31:52
User entered '24 Nov 2020 19:31:47'	System	25 Nov 2020 01:31:52

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-12-01T14:30:32', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c852806d-7c7f-4086-9c95-d1f07f4d0cd7'	System	01 Dec 2020 20:30:53
User entered 'No (N)'	System	01 Dec 2020 20:30:53

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2020-12-01T14:30:42', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c852806d-7c7f-4086-9c95-d1f07f4d0cd7'	System	01 Dec 2020 20:30:53
User entered 'No (N)'	System	01 Dec 2020 20:30:53

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-12-01T14:30:48', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c852806d-7c7f-4086-9c95-d1f07f4d0cd7'	System	01 Dec 2020 20:30:53
User entered '01 Dec 2020 14:30:48'	System	01 Dec 2020 20:30:53

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-12-08T14:29:13', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9fee5968-6bbb-4557-bbf4-d7f40255f0d9'	System	08 Dec 2020 20:29:39
User entered 'No (N)'	System	08 Dec 2020 20:29:39

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2020-12-08T14:29:21', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9fee5968-6bbb-4557-bbf4-d7f40255f0d9'	System	08 Dec 2020 20:29:39
User entered 'No (N)'	System	08 Dec 2020 20:29:39

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-12-08T14:29:32', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9fee5968-6bbb-4557-bbf4-d7f40255f0d9'	System	08 Dec 2020 20:29:39
User entered '08 Dec 2020 14:29:32'	System	08 Dec 2020 20:29:39

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-12-15T11:25:58', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'eb6452d9-53ff-4c6f-9bb6-f93a11c7e809'	System	15 Dec 2020 17:27:06
User entered 'Yes (Y)'	System	15 Dec 2020 17:27:06

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2020-12-15T11:26:17', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'eb6452d9-53ff-4c6f-9bb6-f93a11c7e809'	System	15 Dec 2020 17:27:06
User entered 'No (N)'	System	15 Dec 2020 17:27:06

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-12-15T11:26:25', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'eb6452d9-53ff-4c6f-9bb6-f93a11c7e809'	System	15 Dec 2020 17:27:06
User entered 'No (N)'	System	15 Dec 2020 17:27:06

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-12-15T11:26:36', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'eb6452d9-53ff-4c6f-9bb6-f93a11c7e809'	System	15 Dec 2020 17:27:06
User entered 'No (N)'	System	15 Dec 2020 17:27:06

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-12-15T11:26:59', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'eb6452d9-53ff-4c6f-9bb6-f93a11c7e809' User entered '15 Dec 2020 11:26:59'	System	15 Dec 2020 17:27:06
	System	15 Dec 2020 17:27:06

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-12-19T10:47:57', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f890591e-fcad-4a91-83d3-a7188bb20167'	System	19 Dec 2020 16:49:22
User entered 'Yes (Y)'	System	19 Dec 2020 16:49:22

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2020-12-19T10:48:06', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f890591e-fcad-4a91-83d3-a7188bb20167'	System	19 Dec 2020 16:49:22
User entered 'No (N)'	System	19 Dec 2020 16:49:22

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-12-19T10:48:19', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f890591e-fcad-4a91-83d3-a7188bb20167'	System	19 Dec 2020 16:49:22
User entered 'No (N)'	System	19 Dec 2020 16:49:22

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-12-19T10:49:06', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f890591e-fcad-4a91-83d3-a7188bb20167'	System	19 Dec 2020 16:49:22
User entered 'No (N)'	System	19 Dec 2020 16:49:22

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-12-19T10:49:17', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'f890591e-fcad-4a91-83d3-a7188bb20167'	System	19 Dec 2020 16:49:22
User entered '19 Dec 2020 10:49:17'	System	19 Dec 2020 16:49:22

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2020-12-26T00:21:08', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '30af05ba-9148-47e0-b1c9-47f9b5a4d0b6'	System	26 Dec 2020 06:21:25
User entered 'No (N)'	System	26 Dec 2020 06:21:25

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2020-12-26T00:21:15', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '30af05ba-9148-47e0-b1c9-47f9b5a4d0b6'	System	26 Dec 2020 06:21:25
User entered 'No (N)'	System	26 Dec 2020 06:21:25

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2020-12-26T00:21:21', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '30af05ba-9148-47e0-b1c9-47f9b5a4d0b6'	System	26 Dec 2020 06:21:25
User entered '26 Dec 2020 00:21:21'	System	26 Dec 2020 06:21:25

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-01-02T00:04:57', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9d53ed8b-2dff-496f-bd4b-6df5885762ab'	System	02 Jan 2021 06:05:14
User entered 'No (N)'	System	02 Jan 2021 06:05:14

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-01-02T00:05:04', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9d53ed8b-2dff-496f-bd4b-6df5885762ab'	System	02 Jan 2021 06:05:14
User entered 'No (N)'	System	02 Jan 2021 06:05:14

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-01-02T00:05:09', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '9d53ed8b-2dff-496f-bd4b-6df5885762ab'	System	02 Jan 2021 06:05:14
User entered '02 Jan 2021 00:05:09'	System	02 Jan 2021 06:05:14

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-01-09T05:38:28', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '96a92114-f392-4c40-962b-0d583e5113d4'	System	09 Jan 2021 11:39:09
User entered 'No (N)'	System	09 Jan 2021 11:39:09

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-01-09T05:38:57', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '96a92114-f392-4c40-962b-0d583e5113d4'	System	09 Jan 2021 11:39:09
User entered 'No (N)'	System	09 Jan 2021 11:39:09

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-01-09T05:39:02', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '96a92114-f392-4c40-962b-0d583e5113d4'	System	09 Jan 2021 11:39:09
User entered '09 Jan 2021 05:39:02'	System	09 Jan 2021 11:39:09

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-01-17T16:58:29', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5accb62b-18ee-4d70-8211-a7a77153243e'	System	17 Jan 2021 22:59:26
User entered 'Yes (Y)'	System	17 Jan 2021 22:59:26

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-01-17T16:58:40', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5accb62b-18ee-4d70-8211-a7a77153243e'	System	17 Jan 2021 22:59:26
User entered 'No (N)'	System	17 Jan 2021 22:59:26

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-01-17T16:58:47', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5accb62b-18ee-4d70-8211-a7a77153243e'	System	17 Jan 2021 22:59:26
User entered 'No (N)'	System	17 Jan 2021 22:59:26

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-01-17T16:58:54', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5accb62b-18ee-4d70-8211-a7a77153243e'	System	17 Jan 2021 22:59:26
User entered 'Yes (Y)'	System	17 Jan 2021 22:59:26

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Please 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 (be84ddf470b90ac7)', Time: '2021-01-17T16:59:04', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5accb62b-18ee-4d70-8211-a7a77153243e'	System	17 Jan 2021 22:59:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Jan 2021 22:59:26

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-01-17T16:59:12', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5accb62b-18ee-4d70-8211-a7a77153243e' User entered '17 Jan 2021 16:59:12'	System	17 Jan 2021 22:59:26
	System	17 Jan 2021 22:59:26

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-01-24T12:00:50', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '81a8cbd6-80a9-4ab5-a3c7-444a71cb901f'	System	24 Jan 2021 18:01:54
User entered 'No (N)'	System	24 Jan 2021 18:01:54

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-01-24T12:00:29', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '81a8cbd6-80a9-4ab5-a3c7-444a71cb901f'	System	24 Jan 2021 18:01:54
User entered 'No (N)'	System	24 Jan 2021 18:01:54

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-01-24T12:00:55', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '81a8cbd6-80a9-4ab5-a3c7-444a71cb901f' User entered '24 Jan 2021 12:00:55'	System	24 Jan 2021 18:01:54

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-01-31T10:02:09', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5c37ea3e-fbae-4430-a7c9-01cb3016329d'	System	31 Jan 2021 16:02:31
User entered 'No (N)'	System	31 Jan 2021 16:02:31

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-01-31T10:02:15', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5c37ea3e-fbae-4430-a7c9-01cb3016329d'	System	31 Jan 2021 16:02:31
User entered 'No (N)'	System	31 Jan 2021 16:02:31

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-01-31T10:02:24', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '5c37ea3e-fbae-4430-a7c9-01cb3016329d' User entered '31 Jan 2021 10:02:24'	System	31 Jan 2021 16:02:31
	System	31 Jan 2021 16:02:31

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-02-06T19:10:11', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c4dde398-0de3-4b11-a999-8f5a8f641988'	System	07 Feb 2021 01:10:29
User entered 'No (N)'	System	07 Feb 2021 01:10:29

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-02-06T19:10:03', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c4dde398-0de3-4b11-a999-8f5a8f641988'	System	07 Feb 2021 01:10:29
User entered 'No (N)'	System	07 Feb 2021 01:10:29

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-02-06T19:10:25', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'c4dde398-0de3-4b11-a999-8f5a8f641988'	System	07 Feb 2021 01:10:29
User entered '06 Feb 2021 19:10:25'	System	07 Feb 2021 01:10:29

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-02-13T00:01:46', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e053edc1-8a46-45ac-9809-b92faf7c7111'	System	13 Feb 2021 06:02:18
User entered 'No (N)'	System	13 Feb 2021 06:02:18

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-02-13T00:01:54', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e053edc1-8a46-45ac-9809-b92faf7c7111'	System	13 Feb 2021 06:02:18
User entered 'No (N)'	System	13 Feb 2021 06:02:18

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-02-13T00:01:59', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e053edc1-8a46-45ac-9809-b92faf7c7111' User entered '13 Feb 2021 00:01:59'	System	13 Feb 2021 06:02:18
	System	13 Feb 2021 06:02:18

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-02-20T22:55:07', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '36e77247-d453-457b-9ff2-9e8d18a20e99'	System	21 Feb 2021 04:55:19
User entered 'No (N)'	System	21 Feb 2021 04:55:19

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-02-20T22:55:11', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '36e77247-d453-457b-9ff2-9e8d18a20e99'	System	21 Feb 2021 04:55:19
User entered 'No (N)'	System	21 Feb 2021 04:55:19

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-02-20T22:55:16', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '36e77247-d453-457b-9ff2-9e8d18a20e99'	System	21 Feb 2021 04:55:19
User entered '20 Feb 2021 22:55:16'	System	21 Feb 2021 04:55:19

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-02-28T16:38:02-06:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd0c474f2-e24c-45d9-ba12-0f427d35e9e6'	System	28 Feb 2021 22:38:12
User entered 'No (N)'	System	28 Feb 2021 22:38:12

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-02-28T16:38:05-06:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd0c474f2-e24c-45d9-ba12-0f427d35e9e6'	System	28 Feb 2021 22:38:12
User entered 'No (N)'	System	28 Feb 2021 22:38:12

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-02-28T16:38:08-06:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd0c474f2-e24c-45d9-ba12-0f427d35e9e6'	System	28 Feb 2021 22:38:12
User entered '28 Feb 2021 16:38:08'	System	28 Feb 2021 22:38:12

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-03-07T10:56:43-06:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '6a4a8410-9806-480a-901f-35848c32c9de'	System	07 Mar 2021 16:57:00
User entered 'No (N)'	System	07 Mar 2021 16:57:00

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-03-07T10:56:50-06:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '6a4a8410-9806-480a-901f-35848c32c9de'	System	07 Mar 2021 16:57:00
User entered 'No (N)'	System	07 Mar 2021 16:57:00

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-03-07T10:56:55-06:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '6a4a8410-9806-480a-901f-35848c32c9de' User entered '07 Mar 2021 10:56:55'	System	07 Mar 2021 16:57:00
	System	07 Mar 2021 16:57:00

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-03-14T10:41:52-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'cf877784-31db-42b8-8bd6-13e59efce005'	System	14 Mar 2021 15:42:04
User entered 'No (N)'	System	14 Mar 2021 15:42:04

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-03-14T10:41:57-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'cf877784-31db-42b8-8bd6-13e59efce005'	System	14 Mar 2021 15:42:04
User entered 'No (N)'	System	14 Mar 2021 15:42:04

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-03-14T10:42:00-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'cf877784-31db-42b8-8bd6-13e59efce005'	System	14 Mar 2021 15:42:04
User entered '14 Mar 2021 10:42:00'	System	14 Mar 2021 15:42:04

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-03-21T15:24:58-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8339be7b-afcc-4b01-a6aa-ba51c9d56809' User entered 'No (N)'	System	21 Mar 2021 20:25:28

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-03-21T15:25:05-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8339be7b-afcc-4b01-a6aa-ba51c9d56809' User entered 'No (N)'	System	21 Mar 2021 20:25:28

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-03-21T15:25:08-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '8339be7b-afcc-4b01-a6aa-ba51c9d56809' User entered '21 Mar 2021 15:25:08'	System	21 Mar 2021 20:25:28
	System	21 Mar 2021 20:25:28

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-03-28T20:36:54-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '52b8ae3c-0524-414e-80a4-51fcf161f8ab' User entered 'No (N)'	System	29 Mar 2021 01:37:12
	System	29 Mar 2021 01:37:12

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-03-28T20:37:06-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '52b8ae3c-0524-414e-80a4-51fcf161f8ab'	System	29 Mar 2021 01:37:12
User entered 'No (N)'	System	29 Mar 2021 01:37:12

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-03-28T20:37:09-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '52b8ae3c-0524-414e-80a4-51fcf161f8ab' User entered '28 Mar 2021 20:37:09'	System	29 Mar 2021 01:37:12

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-04-04T21:24:42-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '51a10843-b3b5-49b4-bebd-cb13028382c5'	System	05 Apr 2021 02:26:58
User entered 'No (N)'	System	05 Apr 2021 02:26:58

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-04-04T21:24:49-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '51a10843-b3b5-49b4-bebd-cb13028382c5'	System	05 Apr 2021 02:26:58
User entered 'No (N)'	System	05 Apr 2021 02:26:58

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-04-04T21:24:54-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '51a10843-b3b5-49b4-bebd-cb13028382c5'	System	05 Apr 2021 02:26:58
User entered '04 Apr 2021 21:24:54'	System	05 Apr 2021 02:26:58

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-04-11T13:53:35-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e20f02f5-1987-4b06-8122-f4aae17695af' User entered 'No (N)'	System	11 Apr 2021 18:53:45

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-04-11T13:53:40-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e20f02f5-1987-4b06-8122-f4aae17695af' User entered 'No (N)'	System	11 Apr 2021 18:53:45

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-04-11T13:53:42-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'e20f02f5-1987-4b06-8122-f4aae17695af' User entered '11 Apr 2021 13:53:42'	System	11 Apr 2021 18:53:45
	System	11 Apr 2021 18:53:45

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-04-18T17:47:46-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'afaefe9c-c2e1-4126-bca3-f6713449c286'	System	18 Apr 2021 22:47:58
User entered 'No (N)'	System	18 Apr 2021 22:47:58

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-04-18T17:47:52-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'afaefe9c-c2e1-4126-bca3-f6713449c286'	System	18 Apr 2021 22:47:58
User entered 'No (N)'	System	18 Apr 2021 22:47:58

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-04-18T17:47:54-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'afaefe9c-c2e1-4126-bca3-f6713449c286'	System	18 Apr 2021 22:47:58
User entered '18 Apr 2021 17:47:54'	System	18 Apr 2021 22:47:58

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-04-25T15:36:58-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '622be3de-4779-4054-8587-c84bf48bb310'	System	25 Apr 2021 20:37:23
User entered 'No (N)'	System	25 Apr 2021 20:37:23

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-04-25T15:37:13-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '622be3de-4779-4054-8587-c84bf48bb310'	System	25 Apr 2021 20:37:23
User entered 'No (N)'	System	25 Apr 2021 20:37:23

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-04-25T15:37:17-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '622be3de-4779-4054-8587-c84bf48bb310'	System	25 Apr 2021 20:37:23
User entered '25 Apr 2021 15:37:17'	System	25 Apr 2021 20:37:23

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[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 (be84ddf470b90ac7)', Time: '2021-05-02T18:54:28-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2e12c993-d8e0-4581-b150-e0704b64bad0'	System	02 May 2021 23:54:38
User entered 'No (N)'	System	02 May 2021 23:54:38

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

Have you been exposed to someone with 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 (be84ddf470b90ac7)', Time: '2021-05-02T18:54:31-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2e12c993-d8e0-4581-b150-e0704b64bad0'	System	02 May 2021 23:54:38
User entered 'No (N)'	System	02 May 2021 23:54:38

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-05-02T18:54:34-05:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: '2e12c993-d8e0-4581-b150-e0704b64bad0'	System	02 May 2021 23:54:38
User entered '02 May 2021 18:54:34'	System	02 May 2021 23:54:38

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '05 Nov 2022 00:01'	System	19 Nov 2020 19:26:15

US3572125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:15:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:26:15
Amendment Manager: User entered '09 Nov 2022 23:59'	System	19 Nov 2020 19:26:15

US3572125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:15:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-02-28T16:37:46-06:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd02d27ea-db61-45f9-8029-ad0810a8ef6a'	System	28 Feb 2021 22:37:57
User entered 'No (N)'	System	28 Feb 2021 22:37:57

US3572125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:15:18

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:32:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (be84ddf470b90ac7)', Time: '2021-02-28T16:37:54-06:00', User OID: 'PatientReportedOutcome (US3572125)', ODM File OID: 'd02d27ea-db61-45f9-8029-ad0810a8ef6a' User entered '28 Feb 2021 16:37:54'	System	28 Feb 2021 22:37:57
	System	28 Feb 2021 22:37:57

US3572125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:59
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	25 Nov 2020 01:30:41

US3572125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:59
User entered '24 Nov 2020'	(b) (4) Jackie Ziegler (b) (4)	25 Nov 2020 01:30:41

US3572125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	25 Nov 2020 01:30:41

US3572125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:59
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	25 Nov 2020 01:30:41
	(b) (4)	

US3572125

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:14:59
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	25 Nov 2020 01:30:45

US3572125

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:57:59
User entered 'l'	System	25 Nov 2020 01:30:45

US3572125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:34:55
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:19:03

US3572125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:34:55
User entered '31 Dec 2020'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:19:03

US3572125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:34:55
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:19:03

US3572125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:34:55
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:19:03

US3572125

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:35:00
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:19:08

US3572125

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User entered 'l'	System	31 Dec 2020 22:19:08

US3572125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:20:05

US3572125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '27 Jan 2021'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:20:05

US3572125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:20:05

US3572125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:20:05

US3572125

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	23 Feb 2021 20:34:26

US3572125

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User entered 'l'	System	23 Feb 2021 20:34:26

US3572125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:42

US3572125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '26 Feb 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	26 Feb 2021 18:16:42

US3572125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:42

US3572125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:42

US3572125

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:59

US3572125

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:54
User entered 'l'	System	26 Feb 2021 18:16:59

US3572125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:15

US3572125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:15

US3572125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:15

US3572125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	14 Apr 2021 22:43:15

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 22:43:21

US3572125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:25

US3572125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:25

US3572125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:47

US3572125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:47

US3572125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered '15:10'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:47

US3572125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User entered '8 Apr 2021 15:10'	System	14 Apr 2021 22:43:47

US3572125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:14:13
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Apr 2021 22:43:52

US3572125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 22:43:52

US3572125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:12:17

US3572125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '27 Apr 2021'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:12:17
	(b) (4)	

US3572125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:12:17

US3572125

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:15:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:12:17
	(b) (4)	

US3572125

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:12:22

US3572125

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:15:18

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:12:22

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 15:56:48

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '14:30'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 15:56:48

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '03 Feb 2021 14:30'	System	04 Feb 2021 15:56:48

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 15:56:48

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 15:56:48

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Day 1 (Day 1)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '01 Feb 2021'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '0'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '97'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '%'	System	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '97.5' F	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Jackie Ziegler (b) (4)	04 Feb 2021 21:29:37
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:15:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:11:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Day 2 (Day 2)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '02 Feb 2021'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '0'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered empty.	System	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Jackie Ziegler (b) (4)	04 Feb 2021 21:29:37
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:15:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:28:10

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Day 3 (Day 3)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '0'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered empty.	System	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Jackie Ziegler (b) (4)	04 Feb 2021 21:29:37
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:15:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:41:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Day 4 (Day 4)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '4 Feb 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '1' reason for change: Data Entry Error	(b) (4) Jackie Ziegler (b) (4)	05 Feb 2021 22:19:59
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '97'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '%'	System	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '98.2' F	(b) (4) Jackie Ziegler (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:15:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Feb 2021 21:26:57

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Day 5 (Day 5)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '5 Feb 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'l'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '98'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '%'	System	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '97.4' F	(b) (4) Jackie Ziegler (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4)	05 Feb 2021 22:19:59
	(b) (4)	

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:15:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	05 Feb 2021 22:19:59

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Day 6 (Day 6)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '6 Feb 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'I'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '98'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '%'	System	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '97.0' F	(b) (4) Jackie Ziegler (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:15:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	06 Feb 2021 22:47:19

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Day 7 (Day 7)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '7 Feb 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'I'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '96'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '%'	System	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '97.7' F	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4)	07 Feb 2021 21:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:15:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	07 Feb 2021 21:21:38

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Day 8 (Day 8)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '8 Feb 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'I'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '97'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '%'	System	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '96.7' F	(b) (4) Jackie Ziegler (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4)	08 Feb 2021 22:17:36
	(b) (4)	

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

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Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Mild (Mild)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:15:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'None (None)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	08 Feb 2021 22:17:36

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '03 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

[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 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

[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 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '03 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

[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 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 03 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:15:18

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '0'	System	04 Feb 2021 16:42:17

US3572125

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '10 Sep 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:46:39

US3572125

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '13:40'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:46:39

US3572125

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '10 Sep 2020 13:40'	System	10 Sep 2020 18:46:39

US3572125

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Safety Call (Safety Call)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:46:39

US3572125

Folder: Covid-19 Assessment 10 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:46:39

US3572125

Folder: Covid-19 Assessment 10 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:15:18

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:46:45

US3572125

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '18 Sep 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 17:30:47

US3572125

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '13:20'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 17:30:47

US3572125

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User entered '18 Sep 2020 13:20'	System	18 Sep 2020 17:30:47

US3572125

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Safety Call (Safety Call)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Sep 2020 17:30:47

US3572125

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:15:18

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4)	18 Sep 2020 17:30:47

US3572125

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:15:18

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:26:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	12 Mar 2021 16:06:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:15:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:15:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:15:18

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:15:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:15:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4) (u) (4), (b) (6)	09 Mar 2021 20:35:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:15:18

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	10 Mar 2021 08:00:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 20:35:37
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	09 Mar 2021 20:35:10
' answered with 'no saliva collected ' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 09:14:11
User entered '07 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:15:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:15:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:15:18

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:15:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:15:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:15:18

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:15:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:15:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:15:18

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:15:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:15:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:15:18

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:15:18

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:15:18

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:15:18

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:18:37

US3572125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:42:44

US3572125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:42:44

US3572125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:42:44

US3572125

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User entered 'SICKD1'	System	04 Feb 2021 16:42:44

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '16:45'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User entered '03 Feb 2021 16:45'	System	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '70' in	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54
DataPoint set to visible.	System	04 Feb 2021 16:42:44

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '195' lb	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54
DataPoint set to visible.	System	04 Feb 2021 16:42:44

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '97.5' F	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Temporal'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '101'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User entered 'bpm'	System	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '16'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User entered 'breaths/min'	System	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '138'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User entered 'mmHg'	System	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '87'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User entered 'mmHg'	System	04 Feb 2021 16:43:54

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16

US3572125

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16

US3572125

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:44:10

US3572125

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:44:10

US3572125

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:15:18

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:44:25

US3572125

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:15:18

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '03 Feb 2021'	(b) (4) (u) (4), (b) (6)	04 Feb 2021 16:44:25

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:47

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:47

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:47

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	26 Feb 2021 21:16:47

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:15:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 21:16:58

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:17:04

US3572125

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:15:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:17:04

US3572125

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:15:18

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:17:11

US3572125

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:15:18

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 21:17:11

US3572125

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

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:37

US3572125

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

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:37

US3572125

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

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:37

US3572125

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

Form: Visit Date

Generated On: 10 Jun 2021 08:15:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User entered 'UNBLND_DECIDE'	System	15 Feb 2021 19:18:37

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:51

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:09:56

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:51

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:09:56

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:51

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:51

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:51

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:51

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:18:51

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User entered empty.	System	15 Feb 2021 19:18:51

US3572125

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

Form: Unblinding

Generated On: 10 Jun 2021 08:15:18

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User entered empty.	System	15 Feb 2021 19:18:51

US3572125

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:19:13

US3572125

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 15Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 15Feb2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'Accession # 1F60FST AWB - 939474286270 shipped ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 08:18:11
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 15Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). User entered '15 Feb 2021'	(b) (4), (b) (6)	01 Mar 2021 22:27:21
	(b) (4), (b) (6)	25 Feb 2021 20:11:45
	(b) (4), (b) (6)	15 Feb 2021 19:19:13

US3572125

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '13:02'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:19:13

US3572125

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User entered '15 Feb 2021 13:02'	System	15 Feb 2021 19:19:13

US3572125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:19:23

US3572125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:19:23

US3572125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '13:00'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:19:23

US3572125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:47
User entered '15 Feb 2021 13:00'	System	15 Feb 2021 19:19:23

US3572125

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:15:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:46:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Herpes Simplex II. If yes, please update to reflect the term worsening as appropriate and ensure that the Severity is greater than Grade 1/Mild. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 03:46:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:33:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:33:25
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Herpes Simplex II. If yes, please update to reflect the term worsening as appropriate and ensure that the Severity is greater than Grade 1/Mild. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jackie Ziegler (b) (4) (b) (4)	25 Nov 2020 01:36:52
Data point term sent to Coder	System	25 Nov 2020 01:36:45
Coding entries removed.	Jackie Ziegler (b) (4) (b) (4)	25 Nov 2020 01:36:16
User entered 'HERPES SIMPLEX OUTBREAK-worsening' reason for change: Data Entry Error	Jackie Ziegler (b) (4) (b) (4)	25 Nov 2020 01:36:16
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Herpes Simplex II. If yes, please update to reflect the term worsening as appropriate and ensure that the Severity is greater than Grade 1/Mild. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:32:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 22:06:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 22:06:32
Data point term sent to Coder	System	19 Oct 2020 21:31:42
User entered 'Herpes simplex outbreak'	Jackie Ziegler (b) (4)	19 Oct 2020 21:30:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '10 Oct 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
User entered empty.	System	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	25 Nov 2020 01:37:10
User entered 'No (N)' reason for change: New Information	Jackie Ziegler (b) (4)	25 Nov 2020 01:37:10
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	25 Nov 2020 01:36:16
User entered 'Yes (Y)'	System	25 Nov 2020 01:36:16
	Jackie Ziegler (b) (4)	19 Oct 2020 21:30:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Jackie Ziegler (b) (4)	25 Nov 2020 01:36:16
	(b) (4)	
	Jackie Ziegler (b) (4)	19 Oct 2020 21:30:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
User entered empty.	System	19 Oct 2020 21:30:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
reason for change: New Information	Jackie Ziegler (b) (4)	25 Nov 2020 01:36:16
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4)	
	Jackie Ziegler (b) (4)	19 Oct 2020 21:30:52
	(b) (4)	

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 02:18:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 02:18:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 02:18:00
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 21:30:52
User entered empty.	Jackie Ziegler (b) (4)	19 Oct 2020 21:30:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	25 Nov 2020 02:18:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 02:18:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 02:18:00
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 21:30:52
User entered empty.	Jackie Ziegler (b) (4)	19 Oct 2020 21:30:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
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	25 Nov 2020 02:18:00
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 02:18:00
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 21:30:52
User entered empty.	Jackie Ziegler (b) (4)	19 Oct 2020 21:30:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	05 Apr 2021 02:24:18
Signature has been broken.	(b) (4) (u) (4), (b) (6)	03 Apr 2021 05:37:25
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	05 Apr 2021 02:24:18
Signature has been broken.	(b) (4) (u) (4), (b) (6)	03 Apr 2021 05:41:19
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Per CDM (requery): Response is noted, however there is no record of ConMed during this time(10-Oct-20). please update the ConMed treatment and appropriate details for this AE on Concomitant medication and Vaccination page, else clarify. Thank you' (Site from DM).	(b) (4) (u) (4), (b) (6)	04 Jan 2021 11:32:17
Query 'Per CDM (requery): Response is noted, however there is no record of ConMed during this time(10-Oct-20). please update the ConMed treatment and appropriate details for this AE on Concomitant medication and Vaccination page, else clarify. Thank you' answered with 'valtrex prn ' (Site from DM).	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:23:47
User opened query 'Per CDM (requery): Response is noted, however there is no record of ConMed during this time(10-Oct-20). please update the ConMed treatment and appropriate details for this AE on Concomitant medication and Vaccination page, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 03:10:35
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 03:10:35
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'pt had medication as prn and used it during this time' (Site from DM).	Jackie Ziegler (b) (4) (b) (4)	25 Nov 2020 01:36:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:32:46
User entered 'I'	Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	05 Apr 2021 02:24:18
Signature has been broken.	(b) (4) (u) (4), (b) (6)	03 Apr 2021 05:42:46
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Jackie Ziegler (b) (4) (b) (4)	25 Nov 2020 01:36:16
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
User entered '0'	System	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55
User entered '0'	System	19 Oct 2020 21:30:52

US3572125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:15:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:19:55

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Jan 2021 18:48:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Jan 2021 18:48:36
Data point term sent to Coder	System	31 Dec 2020 22:25:29
User entered 'herpes simplex flare up'	Jackie Ziegler (b) (4)	31 Dec 2020 22:24:41
	(b) (4)	

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '10 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
User entered empty.	System	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '17 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
User entered empty.	System	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 05:29:58
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' answered with 'As per source this was a mild flare up that required Valtrex 1g PRN as treatment. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:23:08
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 05:13:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
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	27 Jan 2021 02:07:21
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	27 Jan 2021 02:07:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Jan 2021 02:07:21
User entered empty.	System	31 Dec 2020 22:24:41
	Jackie Ziegler (b) (4)	31 Dec 2020 22:24:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	27 Jan 2021 02:07:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 02:07:21
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 02:07:21
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 22:24:41
User entered empty.	Jackie Ziegler (b) (4)	31 Dec 2020 22:24:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
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	27 Jan 2021 02:07:21
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 02:07:21
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 22:24:41
User entered empty.	Jackie Ziegler (b) (4)	31 Dec 2020 22:24:41
	(b) (4)	

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'l'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'valtex'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
User entered '0'	System	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01
User entered '0'	System	31 Dec 2020 22:24:41

US3572125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:15:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:20:01

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:11
User entered 'USA-US091-2021-mRNA-1273-P301000010'	System	05 Feb 2021 14:12:06
User entered 'New'	(b) (4), (b) (6)	05 Feb 2021 14:12:06

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol withdrawal syndrome, LLT: Alcohol withdrawal syndrome - version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 13:00:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 13:00:36
Data point term sent to Coder	System	05 Feb 2021 01:35:44
User entered 'Alcohol withdrawals' reason for change: Data Entry Error	Maria Candelario (b) (4)	05 Feb 2021 01:34:42
Data point term sent to Coder	System	19 Jan 2021 21:27:27
User entered 'Subject reported Admission to Hospital, pending medical records'	Maria Candelario (b) (4)	19 Jan 2021 21:27:25

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Maria Candelario (b) (4)	05 Feb 2021 01:34:42
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	19 Jan 2021 21:27:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '10 Jan 2021'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 21:27:25

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '13 Jan 2021'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 21:27:25

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'PV Query: Since the subject was hospitalized for the event of alcohol withdrawals, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:48:34
Query 'PV Query: Since the subject was hospitalized for the event of alcohol withdrawals, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'AFTER REVIEW OF MEDICAL RECORDS THE EVENT WAS GRADED MODERATE. NO HISTORY OF SEIZURES OR DT'S.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:58:33
User opened query 'PV Query: Since the subject was hospitalized for the event of alcohol withdrawals, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 20:43:46
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 01:34:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 01:34:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	05 Feb 2021 01:34:42
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 21:27:25
User entered empty.	Maria Candelario (b) (4) (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Feb 2021 01:34:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 01:34:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Maria Candelario (b) (4)	05 Feb 2021 01:34:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	19 Jan 2021 21:27:25
	Maria Candelario (b) (4)	19 Jan 2021 21:27:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Admitted to ICU? is missing. Please review and reconcile.' (Site from DM).	(b) (4) (u) (4), (b) (6)	15 Feb 2021 12:43:34
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Admitted to ICU? is missing. Please review and reconcile.' answered with 'The subject was not admitted in ICU' (Site from DM).	Maria Candelario (b) (4) (b) (4)	13 Feb 2021 02:35:46
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Admitted to ICU? is missing. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 05:08:14
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 09:21:14
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Data updated' (Site from System).	Maria Candelario (b) (4) (b) (4)	05 Feb 2021 01:38:13
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	19 Jan 2021 21:27:25
User entered 'I'	Maria Candelario (b) (4) (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Alisha Lutat (b) (4)	03 Feb 2021 23:20:39
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	19 Jan 2021 21:27:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Alisha Lutat (b) (4)	03 Feb 2021 23:20:39
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	19 Jan 2021 21:27:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Per CDM: Please update the response for 'Admitted to ICU' as Requires inpatient or prolongation of existing Hospitalization is checked.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 06:41:25
Query 'Per CDM: Please update the response for 'Admitted to ICU' as Requires inpatient or prolongation of existing Hospitalization is checked.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 17:16:27
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Mar 2021 17:16:01
User opened query 'Per CDM: Please update the response for 'Admitted to ICU' as Requires inpatient or prolongation of existing Hospitalization is checked.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:35:58
User entered empty.	Maria Candelario (b) (4) (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Feb 2021 01:34:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 01:34:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	05 Feb 2021 01:34:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 21:27:25
User entered empty.	System	19 Jan 2021 21:27:25
	Maria Candelario (b) (4)	19 Jan 2021 21:27:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Feb 2021 01:34:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 01:34:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	05 Feb 2021 01:34:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 21:27:25
User entered empty.	System	19 Jan 2021 21:27:25
	Maria Candelario (b) (4)	19 Jan 2021 21:27:25
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:15:18

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
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	19 Jan 2021 21:29:33
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	19 Jan 2021 21:29:33
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	19 Jan 2021 21:29:33
User entered empty.	(b) (4)	
	System	19 Jan 2021 21:27:25
	Maria Candelario (b) (4)	19 Jan 2021 21:27:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:54:35
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Jan 2021 21:29:33
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	19 Jan 2021 21:29:33
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Jan 2021 21:27:25
User entered '0'	Maria Candelario (b) (4) (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:54:35
User entered '0'	Maria Candelario (b) (4) (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered '0'	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
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	03 Feb 2021 23:20:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Alisha Lutat (b) (4)	03 Feb 2021 23:20:39
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 21:27:25
User entered empty.	Maria Candelario (b) (4)	19 Jan 2021 21:27:25
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User entered empty.	(b) (4) Maria Candelario (b) (4)	19 Jan 2021 21:27:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:39
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:31:11
User closed query 'Per DM CLR: Narrative indicates that the subject was given Librium, Vitamins and IV Fluids. However, there are no corresponding ConMed record that match the information. Please review and update to record the corresponding medications as appropriate and update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4) (u) (4), (b) (6)	04 Mar 2021 08:59:27
Query 'Per DM CLR: Narrative indicates that the subject was given Librium, Vitamins and IV Fluids. However, there are no corresponding ConMed record that match the information. Please review and update to record the corresponding medications as appropriate and update Other Action Taken. Otherwise, clarify.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 21:55:00
User opened query 'Per DM CLR: Narrative indicates that the subject was given Librium, Vitamins and IV Fluids. However, there are no corresponding ConMed record that match the information. Please review and update to record the corresponding medications as appropriate and update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 04:32:38
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)	16 Feb 2021 19:49:00
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)	16 Feb 2021 19:48:53

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
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 'None Available' (Site from Safety).	Maria Candelario (b) (4)	13 Feb 2021 23:20:25
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).	Maria Candelario (b) (4)	13 Feb 2021 23:20:06
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 Feb 2021 20:44:28
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 Feb 2021 20:44:02
User entered 'SUBJECT HAS HISTORY OF ALCOHOL ABUSE, PRESENTED TO THE ED COMPLAINING OF NAUSEA, HEADACHE, AND HAND TREMORS. PATIENT WAS ADMITTED WITH THE DIAGNOSIS OF ALCOHOL WITHDRAWAL. HE WAS STARTED ON LIBRIUM 25MG PO TID, VITAMINS, AND IV FLUIDS. SUBJECT SYMPTOMS WERE RELIEVED AND PATIENT WAS DISCHARGED HOME ON LIBRIUM 25 MG PO BIDX 5 DAYS, HE WAS ADVISED TO QUIT DRINKING.' reason for change: Data Entry Error	Maria Candelario (b) (4)	05 Feb 2021 01:38:56
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Feb 2021 01:37:57

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Feb 2021 01:37:57
User entered 'Subject has history of alcohol abuse, presented to theED complaining of nausea, headache, and hand tremors. Patient was admitted with the diagnosis of alcohol withdrawal. He was started on Librium 25mg PO TID, vitamins, and IV fluids. Subject symptoms were relieved and patient was discharged home on Librium 25 mg PO BIDX 5 days, he was advised to quit drinking.' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	05 Feb 2021 01:37:57
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Feb 2021 01:34:42
User entered empty.	Maria Candelario (b) (4) (b) (4)	19 Jan 2021 21:27:25

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Feb 2021 01:34:42

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 01:34:42
User entered '0'	System	19 Jan 2021 21:27:25

US3572125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:15:18

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Mar 2021 17:16:01

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:15:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache = 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. If CM # 11 are given please update indication to include. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	01 Mar 2021 06:10:51
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache = 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. If CM # 11 are given please update indication to include. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 19:45:14
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache = 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. If CM # 11 are given please update indication to include. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 06:43:07
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:48:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 18:50:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 18:50:45
Data point term sent to Coder	System	10 Sep 2020 18:50:06
User entered 'Cetirizine'	Jackie Ziegler (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'allergic rhinitis'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'I'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'tablet (TABLET)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'once daily (QD)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '1 Jan 2013'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:49:37
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 18:49:37

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 18:51:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 18:51:40
Data point term sent to Coder	System	10 Sep 2020 18:51:09
User entered 'multivitamin'	Jackie Ziegler (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'dietary supplement'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'I'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'tablet (TABLET)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'once daily (QD)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:50:23
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '1 Jan 2017'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:50:23
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:50:23
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 18:50:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: AZELASTINE HYDROCHLORIDE, PRODUCTSYNONYM: AZELASTINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 01:32:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 01:32:47
Data point term sent to Coder	System	10 Sep 2020 18:52:13
User entered 'azelastine HCL'	Jackie Ziegler (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'allergic rhinitis'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'I'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Other (OTHER)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'spray'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'once daily (QD)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Nasal (NASAL)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:57:25
User entered '1 Aug 2020' reason for change: Data Entry Error	Jackie Ziegler (b) (4)	10 Sep 2020 18:57:25
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:51:26
User entered empty.	System	10 Sep 2020 18:51:26
	Jackie Ziegler (b) (4)	10 Sep 2020 18:51:26
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
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	10 Sep 2020 18:57:25
User entered 'Yes (Y)' reason for change: Data Entry Error	System	10 Sep 2020 18:57:25
User opened query 'Data is required. Please complete.' (Site from System).	Jackie Ziegler (b) (4)	10 Sep 2020 18:57:25
User entered empty.	(b) (4)	
	System	10 Sep 2020 18:51:26
	Jackie Ziegler (b) (4)	10 Sep 2020 18:51:26
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	30 Sep 2020 18:31:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 18:31:31
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	10 Sep 2020 18:57:25
User entered '1 Aug 2020'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:51:26
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 18:51:26

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 12:26:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 12:26:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:33:51
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 18:33:51
Data point term sent to Coder	System	30 Sep 2020 18:33:26
Coding entries removed.	(b) (4), (b) (6)	30 Sep 2020 18:32:25
User entered 'VALCYCLOVIR' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 18:32:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 08:12:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 08:12:40
Data point term sent to Coder	System	10 Sep 2020 18:53:17

PRODUCTION RELEASE (v12.003
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US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Valcyclovier'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'herpes simplex II'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'I'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'g (g)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'as needed (PRN)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:52:45
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:52:45
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '1 Jan 2013'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:52:45
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:52:45

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Sep 2020 18:54:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Sep 2020 18:54:52
Data point term sent to Coder	System	10 Sep 2020 18:54:20
User entered 'trazadone'	Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'insomnia'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered '100'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'mg (mg)'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'once daily (QD)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '1 Jan 2015'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
Signature has been broken.	(b) (4)	
	Jackie Ziegler (b) (4)	27 Apr 2021 19:12:54
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Jackie Ziegler (b) (4)	27 Apr 2021 19:12:54
	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
	(b) (4)	
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
Signature has been broken.	(b) (4)	
	Jackie Ziegler (b) (4)	27 Apr 2021 19:12:54
	(b) (4)	
User entered '3 Mar 2021' reason for change: Data Entry Error	Jackie Ziegler (b) (4)	27 Apr 2021 19:12:54
	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
	(b) (4)	
User entered empty.	Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User entered 'I'	System	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User entered 'I'	System	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:19
User entered '804 (804)'	System	10 Sep 2020 18:53:46

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 06:02:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 06:02:46
Data point term sent to Coder	System	10 Sep 2020 18:55:25
User entered 'ketocanazole'	Jackie Ziegler (b) (4)	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'dandruff'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'I'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Other (OTHER)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:54:55
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'application'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'as needed (PRN)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:54:55
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Topical (TOPICAL)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:54:55
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '1 Jul 2020'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:54:55
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:54:55
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:54:55
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:54:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Sep 2020 18:57:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Sep 2020 18:57:45
Data point term sent to Coder	System	10 Sep 2020 18:56:27
User entered 'Testosterone Cypionate'	Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'low testosterone'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered '100'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'mg (mg)'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'every week (QS)'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'Intramuscular (INTRAMUSCULAR)'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '1 Jul 2020'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
Signature has been broken.	(b) (4)	
	Jackie Ziegler (b) (4)	27 Apr 2021 19:15:34
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Jackie Ziegler (b) (4)	27 Apr 2021 19:15:34
	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
	(b) (4)	
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
Signature has been broken.	(b) (4)	
	Jackie Ziegler (b) (4)	27 Apr 2021 19:15:34
	(b) (4)	
User entered '14 Jan 2021' reason for change: New Information	Jackie Ziegler (b) (4)	27 Apr 2021 19:15:34
	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
	(b) (4)	
User entered empty.	Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User entered 'I'	System	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User entered 'I'	System	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:46:21
User entered '803 (803)'	System	10 Sep 2020 18:56:14

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 18:58:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 18:58:56
Data point term sent to Coder	System	10 Sep 2020 18:57:29
User entered 'famotidine'	Jackie Ziegler (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:58
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'GERD'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '20'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:58
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'twice daily (BID)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '1 Aug 2020'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:58
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:56:58
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 18:56:58

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:47:52
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 18:47:52
Data point term sent to Coder	System	30 Sep 2020 18:46:58
User entered 'FLUTICASONE'	(b) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'ALLERGIC RHINITIS'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'I'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Other (OTHER)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'SPRAY'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'once daily (QD)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Nasal (NASAL)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '01 Aug 2020'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 18:46:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:11:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Feb 2021 00:11:57
Data point term sent to Coder	System	25 Feb 2021 19:40:20
Coding entries removed.	(b) (4), (b) (6)	25 Feb 2021 19:39:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:48:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:48:34
Data point term sent to Coder	System	09 Oct 2020 19:07:12
User entered 'aspirin'	Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'FEVER, PAIN (headache and general joint ache)' reason for change: Data Entry Error	(b) (4)	25 Feb 2021 19:39:55
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 10:09:37
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, PAIN did not meet the AE reporting criteria.' answered with 'noted in source, did not meet AE requirement for medidata' (Site from DM).	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:30:23

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER, PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER, PAIN did not meet the AE reporting criteria.' (Site from DM). User entered 'fever, pain'	(b) (4), (b) (6)	24 Nov 2020 14:29:01
	Jackie Ziegler (b) (4) (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '650'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'as needed (PRN)'	Jackie Ziegler (b) (4) (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '3 Oct 2020'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:39:55
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '4 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	26 Feb 2021 22:07:40
User entered '3 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 19:39:55
User entered empty.	Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User entered empty.	System	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User entered empty.	System	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:23
User entered empty.	System	09 Oct 2020 19:06:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Dec 2020 22:29:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Dec 2020 22:29:20
Data point term sent to Coder	System	31 Dec 2020 22:28:30
User entered 'valtrex'	Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'herpes simplex flare up'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'l'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'g (g)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'as needed (PRN)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '10 Dec 2020'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '18 Dec 2020'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User entered empty.	System	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User entered empty.	System	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:24
User entered empty.	System	31 Dec 2020 22:28:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Dec 2020 22:30:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Dec 2020 22:30:20
Data point term sent to Coder	System	31 Dec 2020 22:29:30
User entered 'valtrex'	Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'herpes simplex flare up'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'l'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'g (g)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'as needed (PRN)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '10 Oct 2020'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '21 Oct 2020'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User entered empty.	System	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User entered empty.	System	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:28
User entered empty.	System	31 Dec 2020 22:29:09

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: PAPILLOMAVIRUS VACCINES, PRODUCT: HPV VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Jan 2021 18:49:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Jan 2021 18:49:33
Data point term sent to Coder	System	31 Dec 2020 22:30:30
User entered 'HPV Vaccine'	Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'herpes simplex prevention'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'l'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'Other (OTHER)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'dose'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'once (ONCE)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'Intramuscular (INTRAMUSCULAR)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '9 Dec 2020'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '9 Dec 2020'	(b) (4) Jackie Ziegler (b) (4)	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	26 Feb 2021 04:37:58
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated as this prophylaxis not for solicited event' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:22:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 01:21:26
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:28:05
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	31 Dec 2020 22:29:53

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EAB) (1725)

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US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User entered empty.	System	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User entered empty.	System	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:29
User entered empty.	System	31 Dec 2020 22:29:53

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: PAPILLOMAVIRUS VACCINES, PRODUCT: HPV VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 22:21:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 22:21:07
Data point term sent to Coder	System	27 Jan 2021 22:19:59
User entered 'HPV Vaccine'	Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'HPV prevention'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'l'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Other (OTHER)'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'dose'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'once (ONCE)'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:30:13
User entered 'Intramuscular (INTRAMUSCULAR)'	Jackie Ziegler (b) (4) (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '18 Jan 2021'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '18 Jan 2021'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User entered empty.	System	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User entered empty.	System	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:35
User entered empty.	System	27 Jan 2021 22:19:54

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: CETIRIZINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC-D - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 12:58:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 12:58:56
Data point term sent to Coder	System	26 Feb 2021 18:17:16
User entered 'zyrtec D (certrizine HCl/Pseudoephedrine)'	Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'allergic rhinitis'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '5/120'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'as needed (PRN)'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '25 Feb 2021'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
Signature has been broken.	(b) (4)	
	Jackie Ziegler (b) (4)	27 Apr 2021 19:18:24
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jackie Ziegler (b) (4)	27 Apr 2021 19:18:24
	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
	(b) (4)	
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
Signature has been broken.	(b) (4)	
	Jackie Ziegler (b) (4)	27 Apr 2021 19:18:24
	(b) (4)	
User entered '3 Mar 2021' reason for change: New Information	Jackie Ziegler (b) (4)	27 Apr 2021 19:18:24
	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
	(b) (4)	
User entered empty.	Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User entered empty.	System	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User entered empty.	System	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:40
User entered empty.	System	26 Feb 2021 18:16:31

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CHLORDIAZEPOXIDE, PRODUCTSYNONYM: LIBRIUM [CHLORDIAZEPOXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:38:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:38:49
Data point term sent to Coder	System	02 Mar 2021 21:59:38
User entered 'Librium'	(b) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Alcohol Withdraws'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '25'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'three times daily (TID)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '10 Jan 2021'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '13 Jan 2021'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User entered '3'	System	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User entered 'I'	System	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:44
User entered '804 (804)'	System	02 Mar 2021 21:59:02

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Mar 2021 02:02:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 02:02:48
Data point term sent to Coder	System	02 Mar 2021 22:02:40
User entered 'VITAMINS'	(b) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Alcohol Withdraws'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'UNK'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Other (OTHER)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'UNK'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'once daily (QD)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '10 Jan 2021'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '13 Jan 2021'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User entered 'I'	System	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User entered 'I'	System	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:49
User entered '804 (804)'	System	02 Mar 2021 22:02:18

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 12:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:15:42
Data point term sent to Coder	System	02 Mar 2021 22:03:41
User entered 'IV FLUID'	(b) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Alcohol Withdraws'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'UNK'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Other (OTHER)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'UNK'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	02 Mar 2021 22:06:00
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	02 Mar 2021 22:06:00
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 22:06:00
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	02 Mar 2021 22:03:21
User entered 'once (ONCE)'	(b) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '10 Jan 2021'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '13 Jan 2021'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User entered 'l'	System	02 Mar 2021 22:06:00
User entered empty.	System	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User entered '1'	System	02 Mar 2021 22:06:00
User entered empty.	System	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:52
User entered '804 (804)'	System	02 Mar 2021 22:06:00
User entered empty.	System	02 Mar 2021 22:03:21

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CHLORDIAZEPOXIDE, PRODUCTSYNONYM: LIBRIUM [CHLORDIAZEPOXIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:38:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:38:49
Data point term sent to Coder	System	02 Mar 2021 22:05:44
User entered 'LIBIRIUM'	(b) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Alcohol Withdraws'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '25'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'twice daily (BID)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '13 Jan 2021'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '0'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '18 Jan 2021'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User entered '2'	System	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User entered 'I'	System	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:48:58
User entered '804 (804)'	System	02 Mar 2021 22:04:55

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 20:12:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 20:12:35
Data point term sent to Coder	System	27 Apr 2021 19:16:05
User entered 'trazadone'	Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'insomnia'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '50'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'once daily (QD)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '3 Mar 2021'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 19:15:00

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 20:13:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Apr 2021 20:13:03
Data point term sent to Coder	System	27 Apr 2021 19:17:07
User entered 'testosterone'	Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'low testosterone'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '80'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'every week (QS)' reason for change:	(b) (4)	
Data Entry Error	Jackie Ziegler (b) (4)	27 Apr 2021 19:17:55
User entered 'other (OTHER)'	(b) (4)	
	Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty; reason for change Data Entry Error	(b) (4)	
	Jackie Ziegler (b) (4)	27 Apr 2021 19:17:55
User entered 'once a week'	(b) (4)	
	Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4) (b) (4)	28 Apr 2021 18:23:15
User entered 'Intramuscular (INTRAMUSCULAR)'	Jackie Ziegler (b) (4) (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '14 Jan 2021'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '12 Mar 2021'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User entered 'I'	System	27 Apr 2021 19:17:55
User entered empty.	System	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User entered 'I'	System	27 Apr 2021 19:17:55
User entered empty.	System	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:49:09
User entered '803 (803)'	System	27 Apr 2021 19:17:55
User entered empty.	System	27 Apr 2021 19:17:04

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 20:13:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 20:13:39
Data point term sent to Coder	System	27 Apr 2021 19:18:15
User entered 'testosterone'	Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'low testosterone'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '60'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'every week (QS)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '12 Mar 2021'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	27 Apr 2021 19:17:41

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 20:14:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 20:14:13
Data point term sent to Coder	System	27 Apr 2021 19:19:17
User entered 'xyzal'	Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'allergic rhinitis'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '5'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'once daily (QD)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '3 Mar 2021'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jackie Ziegler (b) (4)	27 Apr 2021 19:20:40
	(b) (4)	
User entered 'No (N)'	Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15
	(b) (4)	

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered empty; reason for change Data Entry Error	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:20:40
User entered '16 Apr 2021'	Jackie Ziegler (b) (4) (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 18:23:15
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:15:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Apr 2021 19:19:15

US3572125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:15:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:15:30
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	10 Sep 2020 18:47:52

US3572125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:15:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered '8 Sep 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:48:16

US3572125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:15:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User entered 'wart removal- dermatology'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:48:16

US3572125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:15:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (u) (4), (b) (6)	10 Feb 2021 03:48:45
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 21:42:40
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jackie Ziegler (b) (4) (b) (4)	09 Oct 2020 18:55:32
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 15:29:54
User entered 'Medical History (MH)'	Jackie Ziegler (b) (4) (b) (4)	10 Sep 2020 18:48:16

US3572125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:15:18

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:13
User closed query 'Indication is Other, however specify is missing. Please provide.' (Site from System).	(b) (4) System	09 Oct 2020 18:56:02
User entered 'scheduled previously' reason for change: Data Entry Error	Jackie Ziegler (b) (4)	09 Oct 2020 18:56:02
User opened query 'Indication is Other, however specify is missing. Please provide.' (Site from System).	(b) (4) System	09 Oct 2020 18:55:32
User entered empty.	Jackie Ziegler (b) (4)	10 Sep 2020 18:48:16
	(b) (4)	

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'USA-US091-2021-MRNA-1273-P301000010'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Milton'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Haber'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '2344 Laguna Del Mar, Suite 201'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Laredo'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'TX'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '78041'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 20:00:37
User entered 'US'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Mar 2021 16:30:20
User entered '3'	System	03 Mar 2021 16:54:26
User entered '2'	System	16 Feb 2021 20:00:52
User entered '1'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'USA-US091-2021-MRNA-1273-P301000010'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Milton'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Haber'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '2344 Laguna Del Mar, Suite 201'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Laredo'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'TX'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '78041'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 20:00:37
User entered 'US'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Mar 2021 16:30:20
User entered '3'	System	03 Mar 2021 16:54:26
User entered '2'	System	16 Feb 2021 20:00:52
User entered '1'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:15:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '05/Feb/2021 14:12'	(b) (4) System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:15:18

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)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:00:37
User entered 'l'	(b) (4), (b) (6)	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'USA-US091-2021-MRNA-1273-P301000010'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Milton'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Haber'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '2344 Laguna Del Mar, Suite 201'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Laredo'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'TX'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '78041'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 20:00:37
User entered 'US'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Mar 2021 16:30:20
User entered '3'	System	03 Mar 2021 16:54:26
User entered '2'	System	16 Feb 2021 20:00:52
User entered '1'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:15:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '16/Feb/2021 15:00'	(b) (4) System	16 Feb 2021 20:00:52

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:15:18

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)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Mar 2021 16:54:30
User entered 'l'	(b) (4), (b) (6)	16 Feb 2021 20:00:52

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'USA-US091-2021-MRNA-1273-P301000010'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Milton'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Haber'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '2344 Laguna Del Mar, Suite 201'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Laredo'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'TX'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '78041'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 20:00:37
User entered 'US'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Mar 2021 16:30:20
User entered '3'	System	03 Mar 2021 16:54:26
User entered '2'	System	16 Feb 2021 20:00:52
User entered '1'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:15:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '03/Mar/2021 11:54'	(b) (4) System	03 Mar 2021 16:54:26

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:15:18

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)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 16:54:30
User entered 'l'	(b) (4), (b) (6)	03 Mar 2021 16:54:26

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'USA-US091-2021-MRNA-1273-P301000010'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Yes (Y)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'No (N)'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Milton'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Haber'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '2344 Laguna Del Mar, Suite 201'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'Laredo'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered 'TX'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:12:26
User entered '78041'	System	05 Feb 2021 14:12:06

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 20:00:37
User entered 'US'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:15:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Mar 2021 16:30:20
User entered '3'	System	03 Mar 2021 16:54:26
User entered '2'	System	16 Feb 2021 20:00:52
User entered '1'	System	05 Feb 2021 14:12:33

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:15:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
User entered '12/Mar/2021 11:30'	(b) (4) System	12 Mar 2021 16:30:20

US3572125

Folder: SAE USA-US091-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:15:18

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)	20 Apr 2021 15:42:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:30:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:30:23
User entered 'l'	(b) (4), (b) (6)	12 Mar 2021 16:30:20