

US3632154 (Prod: Grady Health System)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:55:49

All time stamps listed in this document are displayed in GMT

US3632154

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 17:58:42

Generated On: 11 Aug 2021 22:55:49

[Participant ID](#)

US3632154

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

US3632154

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Date of Birth (MMM yyyy)	(b) (6) 1982
Age	38
Age Units	YEARS
Age (Derived)	38
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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 Feb 2021 17:58:54

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Date of Informed Consent (<i>dd MMM yyyy</i>)	22 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	TB SHOT ALLERGY
Start date (dd MMM yyyy)	01 JAN 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	ERYTHROMYCIN ALLERGY
Start date (dd MMM yyyy)	01 JAN 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 (3)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	ABILIFY ALLERGY
Start date (dd MMM yyyy)	01 JAN 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	MILD ASTHMA
Start date (dd MMM yyyy)	01 JAN 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	SCHIZOAFFECTIVE BIPOLAR
Start date (dd MMM yyyy)	01 JAN 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	MIGRANES
Start date (dd MMM yyyy)	01 JAN 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	HERPES SIMPLEX VIRUS 2
Start date (dd MMM yyyy)	01 JAN 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) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	INTERMITTENT BACK SPASMS
Start date (dd MMM yyyy)	01 JUN 2005
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)	JUN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	NECK PAIN
Start date (dd MMM yyyy)	01 SEP 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)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	01 JAN 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	01 JAN 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	HIDRADENITIS SUPPURATIVA
Start date (dd MMM yyyy)	01 JAN 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	01 UNK 1990
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)	01 UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	PLANTAR FASCITIS
Start date (dd MMM yyyy)	01 MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	SEVERE OBESITY (BMI: 40.57184)
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	FACIAL ACNE
Start date (dd MMM yyyy)	01 UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 15 Mar 2021 12:23:28

Generated On: 11 Aug 2021 22:55:49

Condition	DERMA FILLER INJECTION
Start date (dd MMM yyyy)	UN 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)	UN AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

US3632154

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:42 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 13:42
Height (<i>xxx.x</i>)	63.5 in
Weight (<i>xxx.x</i>)	232.2 lb
BMI (<i>xxx.x</i>)	40.57184 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 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: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Date of assessment (dd MMM yyyy) 22 OCT 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 17:58:54

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

AESTHETICIAN

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 Feb 2021 17:58:54

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

What was the date of randomization? (dd MMM yyyy) 22 OCT 2020

What was the participant's randomization number? 147270

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) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

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) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

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)	22 OCT 2020
Time of assessment (00:00-23:59)	13:42 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 13:42
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 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) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 15:38
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 22 OCT 2020

What was the treatment time? (00:00-23:59) 15:08 (24 HR)

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

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) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

14:33 (24 HR)

Collection date and time (derived)

22 OCT 2020 14:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Collection date (dd MMM yyyy)			22 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:50	22 OCT 2020 14:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

97.4 °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

22 OCT 2020 15:41

PC Open Date & Time

22 OCT 2020 15:28

PC Close Date & Time

22 OCT 2020 17:58

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	23 OCT 2020 01:25
PC Open Date & Time	22 OCT 2020 18:53
PC Close Date & Time	23 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 23:42

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

25 OCT 2020 18:26

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 21:25

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

28 OCT 2020 00:31

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 11:01

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 15:42

PC Open Date & Time

22 OCT 2020 15:28

PC Close Date & Time

22 OCT 2020 17:58

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

23 OCT 2020 01:25

PC Open Date & Time

22 OCT 2020 18:53

PC Close Date & Time

23 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 23:43

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 OCT 2020 18:26

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 21:26

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

28 OCT 2020 00:31

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

29 OCT 2020 11:02

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 15:42
PC Open Date & Time	22 OCT 2020 15:28
PC Close Date & Time	22 OCT 2020 17:58

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 01:26
PC Open Date & Time	22 OCT 2020 18:53
PC Close Date & Time	23 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

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)

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

Yes ☐

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

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 ☒

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 18:27
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

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 ☒

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 21:26
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

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 ☒

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 00:32
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

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 ☒

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 11:02
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3632154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:58:46

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:46

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	VISIT2

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	14:58 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 14:58
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

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)	19 NOV 2020
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 16:52
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3632154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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

US3632154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	19 NOV 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

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) 19 NOV 2020

What was the treatment time? (00:00-23:59) 16:20 (24 HR)

Treatment Date and Time (derived) 19 NOV 2020 16:20

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

US3632154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Collection date (dd MMM yyyy)			19 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:09	19 NOV 2020 16:09
Nasopharyngeal Swab 2	No		

US3632154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 NOV 2020 16:55

PC Open Date & Time

19 NOV 2020 16:40

PC Close Date & Time

19 NOV 2020 19:10

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	20 NOV 2020 00:48
PC Open Date & Time	19 NOV 2020 20:05
PC Close Date & Time	20 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 NOV 2020 19:58

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 NOV 2020 21:37

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 NOV 2020 16:21

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

23 NOV 2020 18:44

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 NOV 2020 20:58

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 NOV 2020 17:38

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

19 NOV 2020 16:56

PC Open Date & Time

19 NOV 2020 16:40

PC Close Date & Time

19 NOV 2020 19:10

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

20 NOV 2020 00:49

PC Open Date & Time

19 NOV 2020 20:05

PC Close Date & Time

20 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

20 NOV 2020 19:58

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

21 NOV 2020 21:38

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

22 NOV 2020 16:22

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

23 NOV 2020 18:45

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

24 NOV 2020 20:58

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

25 NOV 2020 17:39

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 16:56
PC Open Date & Time	19 NOV 2020 16:40
PC Close Date & Time	19 NOV 2020 19:10

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

No ☒

Yes ☐

PC Time stamp	20 NOV 2020 00:49
PC Open Date & Time	19 NOV 2020 20:05
PC Close Date & Time	20 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

		Yes <input type="checkbox"/>
PC Time stamp	20 NOV 2020 19:59	
PC Open Date & Time	20 NOV 2020 12:00	
PC Close Date & Time	21 NOV 2020 11:59	

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

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 ☒

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	21 NOV 2020 21:39
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 16:22
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

114 of 3409

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	23 NOV 2020 18:45
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

116 of 3409

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	24 NOV 2020 20:59
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

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 ☒

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

Yes <input type="checkbox"/>	
PC Time stamp	25 NOV 2020 17:39
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3632154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 DEC 2020

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

Comments ILLNESS VISIT WAS TODAY SO
CONTACT WAS MADE BUT IT
WAS NOT A SAFETY CALL.
If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

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) _____

US3632154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

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.

US3632154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3632154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:55

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 61
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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 68
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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 75
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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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	13 JAN 2021 10:20:05
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 20:56:40

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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	23 JAN 2021 10:24:20
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 09:35:42

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 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 FEB 2021 17:19:32
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

14 FEB 2021 18:26:30

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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	24 FEB 2021 20:54:51
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

28 FEB 2021 21:44:01

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 00:30:06

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

17 MAR 2021 12:19:19

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

22 MAR 2021 19:27:01

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 09:34:12

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 23:35:33

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

13 APR 2021 18:00:06

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

18 APR 2021 23:07:50

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 11:08:12

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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 MAY 2021 00:01:45
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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16 FEB 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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19 FEB 2022 00:01

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23 FEB 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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26 FEB 2022 00:01

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02 MAR 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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12 MAR 2022 00:01

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16 MAR 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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23 MAR 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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30 MAR 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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04 JUN 2022 00:01

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08 JUN 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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11 JUN 2022 00:01

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15 JUN 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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22 JUN 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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20 JUL 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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27 JUL 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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03 AUG 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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

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10 AUG 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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13 AUG 2022 00:01

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17 AUG 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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20 AUG 2022 00:01

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24 AUG 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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31 AUG 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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07 SEP 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 691

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

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

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

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

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

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

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

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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10 SEP 2022 00:01

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14 SEP 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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21 SEP 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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28 SEP 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

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05 OCT 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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°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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	10 DEC 2022 00:01
Patient Cloud Close Date & Time	14 DEC 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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 <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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

17 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2022 23:59

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

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

[Patient Cloud Close Date & Time](#)

28 DEC 2022 23:59

US3632154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:55:49

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
Yes	Yes	28 FEB 2021 21:44:18

US3632154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:44:12

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:44:12

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3632154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3632154

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

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.

US3632154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3632154

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Date of Contact	9 DEC 2020
Time of Contact	12:35
Date and Time of Contact (derived)	9 DEC 2020 12:35
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 checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	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	9 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

Date	10 DEC 2020
------	-------------

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

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

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

Temperature	98.9 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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"/>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 09 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 09 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 09 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 09 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

Date	14 DEC 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	100.3 F
-------------	---------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 09 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 DEC 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

Date	18 DEC 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 ☐

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

Date	21 DEC 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.6 F
-------------	--------

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

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

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

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

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Form: Symptom Log (14)

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

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Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 17:58:44

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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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Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (15)

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Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	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 (15)

Data signed: (b) (4) 22 Feb 2021 17:58:44

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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 09 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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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Form: Symptom Log (17)

Data signed: (b) (4) 22 Feb 2021 17:58:44

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

Date	24 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (17)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

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Form: Symptom Log (18)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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Form: Symptom Log (18)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

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

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

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

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

Temperature	98.4 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Date of Visit	10 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	10 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 22 Apr 2021 15:44:12

Generated On: 11 Aug 2021 22:55:49

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 15 DEC 2020

End Date 15 DEC 2020

Oxygen Saturation 92 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 22 Apr 2021 15:44:12

Generated On: 11 Aug 2021 22:55:49

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 22 Apr 2021 15:44:12

Generated On: 11 Aug 2021 22:55:49

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 DEC 2020
Day 5	Yes	14 DEC 2020
Day 7	Yes	16 DEC 2020
Day 9	Yes	18 DEC 2020
Day 14	Yes	23 DEC 2020
Day 21	No	
Day 28	Yes	6 JAN 2021

US3632154

Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 11 Aug 2021 22:55:49

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3632154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 DEC 2020
Time of assessment (00:00-23:59)	15:22 (24 HR)
Vital Signs Date and Time (derived)	10 DEC 2020 15:22
Height (xxx.x)	63.5 in
Weight (xxx.x)	226.4 lb
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3632154

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 DEC 2020

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

US3632154

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 DEC 2020

US3632154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3632154

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

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.

US3632154

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:55:49

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 JAN 2021
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 12:05
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 JAN 2021

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

US3632154

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

6 JAN 2021

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Height (<i>xxx.x</i>)	
Weight (<i>xxx.x</i>)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

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.

US3632154

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:55:49

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3632154

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

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

Visit date (dd MMM yyyy)	22 JAN 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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US3632154

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 01:38:36

Generated On: 11 Aug 2021 22:55:49

Date of updated informed consent (<i>dd MMM yyyy</i>)	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3632154

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Height	62.5 in
Weight	225 lb
BMI (xxx.x)	40.58190

US3632154

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Height	62.5 in
Weight	225 lb
BMI (xxx.x)	40.58190
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 09:50
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3632154

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Height	62.5 in
Weight	225 lb
BMI (xxx.x)	40.58190
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)	22 JAN 2021
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 11:25
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3632154

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

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.

US3632154

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

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	22 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3632154

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 10:50

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

US3632154

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00-23:59)	10:32 (24 HR)
Collection date and time (derived)	22 JAN 2021 10:32

US3632154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	10:34
Collection Date and Time (derived)	22 JAN 2021 10:34

US3632154

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:54

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

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Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

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)	18 FEB 2021
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 14:19
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

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)	18 FEB 2021
Time of assessment (00:00-23:59)	15:47 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 15:47
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3632154

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3632154

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	18 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3632154

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 18 FEB 2021

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

Treatment Date and Time (derived) 18 FEB 2021 15:15

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

What was the frequency of the study treatment dosing? ONCE

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

US3632154

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632154

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

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) _____

US3632154

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

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.

US3632154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	14:39 (24 HR)
Collection date and time (derived)	18 MAR 2021 14:39

US3632154

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 17:58:42

Generated On: 11 Aug 2021 22:55:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

AEID

Adverse event

TWO SMALL BILATERAL
PLEURAL EFFUSIONS

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)

5 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

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	False
Concomitant Procedure	True
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	

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

PARTICIPANT REPORTED SHE
HAD A CERVICAL SPINE AND
THORACIC SPINE X-RAY ON
29OCT2020 FOR HER BACK
SPASMS AND NECK PAIN. THE
C-RAYS DEMONSTRATED A
GROWTH ON THE PITUITARY
GLAND. THE DOCTOR THEN
ORDERED A CHEST X-RAY ON
05NOV2020 WHICH
DEMONSTRATED TWO SMALL
BILATERAL PLEURAL
EFFUSIONS.

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3632154

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

AEID

Adverse event

CHEST TIGHTNESS (COVID-19
RELATED)

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)

9 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)

22 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 ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT HAD CHEST TIGHTNESS AND WAS SEEN IN THE ED. SHE WAS DIAGNOSED WITH COVID-19 AND DISCHARGED.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 01:19:29

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

AEID	USA-US120-2020-MRNA-1273-P30 1000011
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	8 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

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 type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3632154

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 01:19:29

Generated On: 11 Aug 2021 22:55:49

PARTICIPANT WAS SEEN IN ED
09DEC FOR SHORTNESS OF
BREATH AND CHEST
TIGHTNESS, WAS DIAGNOSED
WITH COVID-19 AND
DISCHARGED HOME. SEEN
FOLLOWING DAY BY STUDY
STAFF FOR ILLNESS VISIT

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

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

Yes ☒

No ☐

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

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication LITHIUM

Prophylaxis Yes ☐
No ☒

Indication SCHIZOAFFECTIVE BIPOLAR

Dose per administration 450

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 OCT 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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication SCHIZOAFFECTIVE BIPOLAR

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 (2)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 OCT 2017
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 06 MAR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication COGENTIN

Prophylaxis Yes ☐
No ☒

Indication SCHIZOAFFECTIVE BIPOLAR

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 OCT 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 (4)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication INVEGA SUSTENNA

Prophylaxis Yes ☐
No ☒

Indication SCHIZOAFFECTIVE BIPOLAR

Dose per administration 234

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) 22 Apr 2021 15:44:11

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	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)		01 OCT 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 checked="" 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) 22 Apr 2021 15:44:11

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Name of Medication NEMENDA

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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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)		01 UNK 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (6)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication HERPES SIMPLEX 2

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	01 JUN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (7)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication ZANAFLEX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES, BACK SPASMS

Dose per administration 4-8

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) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	01 UNK 2005	
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 (8)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication FLEXERIL (CYCLOBENZAPRINE HCL)

Prophylaxis Yes ☐
No ☒

Indication BACK SPAMS, BACK PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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	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)	01 UNK 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 (9)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication REPLAX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 UNK 2005
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 (10)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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Name of Medication TORODOL

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 30

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 (10)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	01 UNK 2005	
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 (11)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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Name of Medication COMPAZINE

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	01 UNK 2005	
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 (12)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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Name of Medication INDOMETHACIN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

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 (12)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 UNK 2012
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 (13)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication MILD ASTHMA

Dose per administration 90

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) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	01 UNK 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 (14)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 UNK 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 (15)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication COLACE

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWEL SYNDROME

Dose per administration 250

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 (15)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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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)	01 UNK 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)	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 (16)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication MILK THISTLE

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 324

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 (16)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	01 UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (17)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 UNK 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (18)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication RISTELA [L-ARGININE,
L-CITRULLINE, ROSAVITA
ROSE HIPS EXTRACT,
PCYNOGENOL FRENCH
MARITIME PINE BARK
EXTRACT]

Prophylaxis Yes ☒
No ☐

Indication WOMEN HEALTH'S

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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Name of Medication PROBIOTIC

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWEL SYNDROME

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication ACCUTANE

Prophylaxis Yes ☐
No ☒

Indication HIDRADENITIS SUPPURATIVA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	01 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)	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 (21)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication BENZOYL PEROXIDE (5%
STRENGTH)

Prophylaxis Yes ☐
No ☒

Indication HIDRADENITIS SUPPURATIVA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 UNK 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication CLINDAMYCIN 1%/30G

Prophylaxis Yes ☐
No ☒

Indication HIDRADENITIS SUPPURATIVA

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 (22)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	01 UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (23)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication NYSTATIN 1,000UNIT/GRAM

Prophylaxis Yes ☐
No ☒

Indication HIDRADENITIS SUPPURATIVA

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 (23)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 UNK 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (24)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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Name of Medication TRIAMCINOLONE .1%/15G

Prophylaxis Yes ☐
No ☒

Indication HIDRADENITIS SUPPURATIVA

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 (24)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	01 UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (25)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 220

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 (25)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	01 UNK 2010	
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 (26)

Data signed: (b) (4) 22 Apr 2021 15:44:11

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Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify EVERY 90 DAYS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	UN UNK 2014	
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"/>

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication NECK PAIN

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication HYDROCORTISONE CREME 2.5 %

Prophylaxis Yes ☐
No ☒

Indication FACIAL ACNE

Dose per administration 1

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

If dose unit is Other, specify THIN LAYER ON FACE

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 (28)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication PEARL CREME

Prophylaxis Yes ☐
No ☒

Indication FACIAL ACNE

Dose per administration 1

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

If dose unit is Other, specify LIGHT LAYER ON FACE

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 (29)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 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)		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 (30)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication TRUVADA

Prophylaxis Yes ☒
No ☐

Indication PREVENT HIV INFECTION

Dose per administration 200-300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		01 UNK 2019
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 (31)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication CODEINE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID 19

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 (31)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		9 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) 9 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 (32)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication ALEVE (NAPROXEN)

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 220

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		12 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) 12 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 (33)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication AJOVY

Prophylaxis Yes ☒
No ☐

Indication MIGRAINES

Dose per administration 225

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 (33)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)	18 FEB 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 checked="" 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 (34)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

Name of Medication ACCUTANE

Prophylaxis Yes ☐
No ☒

Indication FACIAL ACNE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 22 Apr 2021 15:44:11

Generated On: 11 Aug 2021 22:55:49

	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)		05 APR 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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Feb 2021 17:58:44

Generated On: 11 Aug 2021 22:55:49

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
03 NOV 2020	INTRAUTERINE DEVICE INSERTION	Other	PARTICIPANT HAD MIRENA INTRAUTERINE DEVICE INSERTION.
29 OCT 2020	CERVICAL SPINE X-RAY	Adverse Event	
29 OCT 2020	THORACIC SPINE X-RAY	Adverse Event	
5 NOV 2020	CHEST X-RAY	Adverse Event	
25 NOV 2020	THORACENTESIS	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:55:49

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:55:49

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 ☐

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Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

SAEID	USA-US120-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

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Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

SAEID	USA-US120-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/DEC/2020 10:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

SAEID	USA-US120-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/JAN/2021 20:44
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

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Feb 2021 17:58:45

Generated On: 11 Aug 2021 22:55:49

SAEID	USA-US120-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/JAN/2021 11:24
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

US3632154 (Prod: Grady Health System)

US3632154

Form: Participant Creation

Generated On: 11 Aug 2021 22:55:49

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'US3632154'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	22 Oct 2020 17:08:32

US3632154

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:32:25

US3632154

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 17:08:33

US3632154

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Clinic (Clinic)'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:32:25

US3632154

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'SCRN'	System	22 Oct 2020 18:32:25

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1982. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 11:05:01
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1982. Please clarify the subject's Year of Birth and update as appropriate.' answered with 'All genders & years of birth match on our end in the eCRF, GCL, and CRF. Please provide more clarity as to how we can rectify this query.' (Site from DM).	Kelly Likos (b) (4) (b) (4)	02 Nov 2020 17:27:10
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1982. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 21:54:36
User entered (b) (6) 1982'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 17:08:34

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	23 Oct 2020 13:53:28
User entered '38' reason for change: Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 13:53:28
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 13:52:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 13:52:03
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	23 Oct 2020 13:52:03
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	23 Oct 2020 13:52:03
User entered '32' reason for change: Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 13:52:03
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 18:41:53
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	22 Oct 2020 18:41:53
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'YEARS'	System	23 Oct 2020 13:52:03
User entered empty.	System	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '38'	System	22 Oct 2020 18:42:06

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:25:57
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' answered with 'All genders & years of birth match on our end in the eCRF, GCL, and CRF. Please provide more clarity as to how we can rectify this query.' (Site from DM).	Kelly Likos (b) (4) (b) (4)	02 Nov 2020 17:27:27
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 14:26:24
User entered 'Female (F)'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'I'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:55:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:41:53

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:06

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Oct 2020'	System	22 Oct 2020 18:42:06

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2020'	System	22 Oct 2020 18:42:06

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Amendment 4 (4)'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:06

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:06

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:06

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:06

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:06

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 17:08:33

US3632154

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:55:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'I'	System	22 Oct 2020 18:42:11

US3632154

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:11

US3632154

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:55:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:36:32

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Allergy to vaccine, LLT: Allergy to vaccine - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 08:35:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 08:35:01
Data point term sent to Coder	System	23 Oct 2020 13:54:40
User entered 'TB Shot Allergy'	Aastha KC (b) (4)	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	23 Oct 2020 13:54:50
User entered '01 Jan 1997' reason for change: Data Entry Error	System	23 Oct 2020 13:54:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 13:54:50
User entered ' Jan 1997' (non-conformant).	(b) (4)	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 1997'	System	23 Oct 2020 13:54:50
User entered empty.	System	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '1997'	System	23 Oct 2020 13:54:50
User entered empty.	System	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 13:54:39

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 13:58:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 13:58:39
Data point term sent to Coder	System	23 Oct 2020 13:57:42
User entered 'Erythromycin Allergy'	Aastha KC (b) (4)	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Jan 2000'	Aastha KC (b) (4)	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 2000'	System	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2000'	System	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 13:56:54

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:58:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:58:29
Data point term sent to Coder	System	23 Oct 2020 13:57:43
User entered 'Abilify Allergy'	Aastha KC (b) (4)	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Oct 2020 14:04:24
User entered '01 Jan 2017' reason for change: Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 14:04:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Oct 2020 13:57:42
User entered '01 Jan 2017' (non-conformant).	Aastha KC (b) (4)	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 2017'	System	23 Oct 2020 14:04:24
User entered empty.	System	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2017'	System	23 Oct 2020 14:04:24
User entered empty.	System	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 13:57:42

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:05:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:05:28
Data point term sent to Coder	System	23 Oct 2020 14:04:49
User entered 'MILD ASTHMA'	Aastha KC (b) (4)	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Jan 1992'	Aastha KC (b) (4)	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 1992'	System	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '1992'	System	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:04:46

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Psychiatric disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder bipolar type, LLT: Schizoaffective disorder bipolar type - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:13:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:13:39
Data point term sent to Coder	System	23 Oct 2020 14:05:50
User entered 'SCHIZOAFFECTIVE BIPOLAR'	Aastha KC (b) (4)	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Jan 2009'	Aastha KC (b) (4)	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 2009'	System	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2009'	System	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:05:29

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:07:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:07:35
Data point term sent to Coder	System	23 Oct 2020 14:06:51
User entered 'MIGRANES'	Aastha KC (b) (4)	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Jan 1990'	Aastha KC (b) (4)	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 1990'	System	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '1990'	System	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:06:01

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
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)	23 Oct 2020 14:07:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:07:34
Data point term sent to Coder	System	23 Oct 2020 14:06:51
User entered 'Herpes simplex virus 2'	Aastha KC (b) (4)	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Jan 2018'	Aastha KC (b) (4)	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 2018'	System	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2018'	System	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:06:35

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 21:42:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 21:42:00
Data point term sent to Coder	System	14 Jan 2021 21:41:32
Coding entries removed.	(b) (4), (b) (6)	14 Jan 2021 21:41:04
User entered 'Intermittent BACK SPASMS' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 21:41:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:08:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:08:37
Data point term sent to Coder	System	23 Oct 2020 14:07:52
User entered 'Back Spasms'	Aastha KC (b) (4)	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Jun 2005' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:41:04
User entered '01 Jun 2019'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jun 2005'	System	14 Jan 2021 21:41:04
User entered 'Jun 2019'	System	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2005'	System	14 Jan 2021 21:41:04
User entered '2019'	System	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:07:48

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:11:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:11:36
Data point term sent to Coder	System	23 Oct 2020 14:09:56
User entered 'Neck Pain'	Aastha KC (b) (4)	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Sep 2020'	Aastha KC (b) (4)	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Sep 2020'	System	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2020'	System	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:09:54

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:11:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:11:37
Data point term sent to Coder	System	23 Oct 2020 14:10:58
User entered 'Irritable bowel syndrome'	Aastha KC (b) (4)	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Jan 1997'	Aastha KC (b) (4)	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 1997'	System	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '1997'	System	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:10:26

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:14:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:14:32
Data point term sent to Coder	System	23 Oct 2020 14:14:04
User entered 'Seasonal Allergies'	Aastha KC (b) (4)	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Jan 2011'	Aastha KC (b) (4)	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	23 Oct 2020 17:51:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 17:51:47
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	23 Oct 2020 14:13:45
User entered 'No (N)'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 2011'	System	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2011'	System	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:13:45

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Hidradenitis, LLT: Hidradenitis suppurativa - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:26:41
Data point term sent to Coder	System	23 Oct 2020 14:25:29
User entered 'Hidradenitis Suppurativa'	Aastha KC (b) (4)	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 Jan 1997'	Aastha KC (b) (4)	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 1997'	System	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '1997'	System	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:25:05

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:28:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:28:34
Data point term sent to Coder	System	23 Oct 2020 14:27:34
User entered 'Tonsillectomy'	Aastha KC (b) (4)	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 UNK 1990'	Aastha KC (b) (4)	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 UNK 1990'	Aastha KC (b) (4)	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 1990'	System	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '1990'	System	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 1990'	System	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '1990'	System	23 Oct 2020 14:26:52

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Plantar fasciitis, LLT: Plantar fasciitis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:28:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 14:28:34
Data point term sent to Coder	System	23 Oct 2020 14:27:37
User entered 'Plantar Fascitis'	Aastha KC (b) (4)	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 May 2020'	Aastha KC (b) (4)	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'May 2020'	System	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2020'	System	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	23 Oct 2020 14:27:20

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 16:31:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 16:31:22
Data point term sent to Coder	System	05 Nov 2020 15:34:14
User entered 'Severe Obesity (BMI: 40.57184)'	(b) (4), (b) (6)	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	05 Nov 2020 15:34:10

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 22:08:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 22:08:48
Data point term sent to Coder	System	19 Nov 2020 22:08:10
User entered 'facial acne'	Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:08:09

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '01 UNK 1994'	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:08:09

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:08:09
	(b) (4)	

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:08:09
	(b) (4)	

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:08:09
	(b) (4)	

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:08:09

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Jan 1994'	System	19 Nov 2020 22:08:09

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '1994'	System	19 Nov 2020 22:08:09

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	19 Nov 2020 22:08:09

US3632154

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	19 Nov 2020 22:08:09

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User closed query 'Re-query: PER CDM; Kindlyconfirm the medication log line in concomitant medications.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:28:42
Query 'Re-query: PER CDM; Kindlyconfirm the medication log line in concomitant medications.' answered with 'This procedure was prior to the participant starting on the study. This is therefore considered a part of medical history. It was also entered here based on the instructions provided when entering dermal injections. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:20:13
User opened query 'Re-query: PER CDM; Kindlyconfirm the medication log line in concomitant medications.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 06:22:44
User closed query 'Per MM: Please move this medication to CM listings.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 06:22:44
Query 'Per MM: Please move this medication to CM listings.' answered with 'According to the instructions provided by Moderna, if derma fillers were received prior to joining the study they should be listed in Med History. This participant was enrolled in Oct 2020, therefore, this should not be listed in Con Meds. Please let us know if this is incorrect. ' (Site from DM).	Sarah Wiatrek (b) (4)	31 Mar 2021 14:47:12
User opened query 'Per MM: Please move this medication to CM listings.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:13:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 09:13:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 09:13:40
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:23:28
Data point term sent to Coder	System	11 Mar 2021 15:16:28
User entered 'Derma filler injection' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 15:16:12
Data point term sent to Coder	System	11 Mar 2021 14:36:41

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Condition](#)

Audit	User	Time (GMT)
User entered 'Cosmetic filler'	(b) (4), (b) (6)	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:23:28
User entered 'un Aug 2020'	(b) (4), (b) (6)	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:23:28
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:23:28
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:23:28
User entered 'un Aug 2020'	(b) (4), (b) (6)	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	15 Mar 2021 12:23:28
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Aug 2020'	System	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2020'	System	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'Aug 2020'	System	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:55:49

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '2020'	System	11 Mar 2021 14:36:16

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '13:42'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '22 Oct 2020 13:42'	System	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '63.5' in	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37
DataPoint set to visible.	System	22 Oct 2020 18:42:11

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '232.2' lb	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37
DataPoint set to visible.	System	22 Oct 2020 18:42:11

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User closed query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:19:15
Query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' answered with 'Severe obesity will be added to medical history ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:33:28
User opened query 'Per CDM: Please confirm if Height and Weight values are correct. BMI suggests patient has Severe Obesity. If so, please update Medical History. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:39:59
User entered '40.57184'	System	22 Oct 2020 20:42:37
DataPoint set to visible.	System	22 Oct 2020 18:42:11

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'kg/m2'	System	22 Oct 2020 20:42:37
DataPoint set to visible.	System	22 Oct 2020 18:42:11

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered missing code ND - Not Done.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered missing code ND - Not Done.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'bpm'	System	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered missing code ND - Not Done.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'breaths/min'	System	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered missing code ND - Not Done.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'mmHg'	System	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered missing code ND - Not Done.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'mmHg'	System	22 Oct 2020 20:42:37

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21

US3632154

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21

US3632154

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:37

US3632154

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:37

US3632154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:24:58

US3632154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:49

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:24:58

US3632154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:49

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:24:58

US3632154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:49

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:24:58

US3632154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:24:58

US3632154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:49

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:24:58

US3632154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:24:58

US3632154

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:55:49

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:24:58

US3632154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:26:11

US3632154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:26:11

US3632154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Urine (URINE)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:26:11

US3632154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Negative (NEGATIVE)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:26:11

US3632154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Per CDM: 'Was FSH sample collected?' is "No", however 'Collection date' and 'Collection time' is recorded. Please update or clarify accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 04:29:52
Query 'Per CDM: 'Was FSH sample collected?' is "No", however 'Collection date' and 'Collection time' is recorded. Please update or clarify accordingly ' answered with 'No' (Site from DM).	Kelly Likos (b) (4) (b) (4)	03 Nov 2020 14:04:46
User opened query 'Per CDM: 'Was FSH sample collected?' is "No", however 'Collection date' and 'Collection time' is recorded. Please update or clarify accordingly ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 17:12:42
User entered 'No (N)'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:26:11

US3632154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty; reason for change Data Entry Error	Kelly Likos (b) (4)	03 Nov 2020 14:04:41
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:26:11

US3632154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty; reason for change Data Entry Error	Kelly Likos (b) (4)	03 Nov 2020 14:04:41
User entered '13:54'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:26:11

US3632154

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	03 Nov 2020 14:04:41
User entered '22 Oct 2020 13:54'	System	22 Oct 2020 20:26:11

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Aesthetician'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '0'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'I'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:55:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'grocery store, shopping, restaurants, bar'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:28:17

US3632154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:22

US3632154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:22

US3632154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Clinic (Clinic)'	Sarah Wiatrek (b) (4)	22 Oct 2020 18:42:22

US3632154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'VISIT1'	System	22 Oct 2020 18:42:22

US3632154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 18:08:51

US3632154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '147270'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 18:08:51

US3632154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 18:08:51

US3632154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:25

US3632154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:25

US3632154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:25

US3632154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:25

US3632154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:25

US3632154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:25
DataPoint set to visible.	(b) (4) System	22 Oct 2020 18:42:06

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 04:36:10
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and Visit day 1 were done on the same day. Height and weight have been updated to ND. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:18:18
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	13 Nov 2020 18:18:15
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 21:29:32
User entered '63.5' in	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	13 Nov 2020 18:18:15
User entered '232.2' lb	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 04:36:10
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and Visit day 1 were done on the same day. Height and weight have been updated to ND. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:18:18
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	13 Nov 2020 18:18:15
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 21:29:32
User entered '63.5' in	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	13 Nov 2020 18:18:15
User entered '232.2' lb	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '13:42'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '22 Oct 2020 13:42'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '97.2' F	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Oral (Oral)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '65'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'bpm'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '16'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'breaths/min'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '125'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'mmHg'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '80'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'mmHg'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 04:36:10
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Screening and Visit day 1 were done on the same day. Height and weight have been updated to ND. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:18:18
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	13 Nov 2020 18:18:15
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 16-17, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 21:29:32
User entered '63.5' in	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	13 Nov 2020 18:18:15
User entered '232.2' lb	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '15:38'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '22 Oct 2020 15:38'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '97.4' F	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Oral (Oral)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '72'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'bpm'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '20'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'breaths/min'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '132'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'mmHg'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '85'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'mmHg'	System	22 Oct 2020 20:47:46

US3632154

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:21:21

US3632154

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:21:21

US3632154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Per CDM: As per CCG, "If Screening visit and Dosing are done on the same day then Pregnancy test should only be completed at the 'Screening Visit' and marked as "NO" at V1D1 to avoid duplication". Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 05:16:39
Query 'Per CDM: As per CCG, "If Screening visit an Dosing are done on the same day then Pregnancy test should only be completed at the 'Screening Visit' and marked as "NO" at V1D1 to avoid duplication". Please review and update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 22:29:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 22:29:02
User opened query 'Per CDM: As per CCG, "If Screening visit and Dosing are done on the same day then Pregnancy test should only be completed at the 'Screening Visit' and marked as "NO" at V1D1 to avoid duplication". Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 06:50:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Aastha KC (b) (4)	13 Nov 2020 20:56:17
User closed query 'Per CDM: As Per CCG, if Screening and dosing are done on the same day, pregnancy test page should be marked as 'No' at V1D1 to avoid duplication. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:08:37
Query 'Per CDM: As Per CCG, if Screening and dosing are done on the same day, pregnancy test page should be marked as 'No' at V1D1 to avoid duplication. Please update accordingly. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:16:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:16:04

US3632154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: As Per CCG, if Screening and dosing are done on the same day, pregnancy test page should be marked as 'No' at VID1 to avoid duplication. Please update accordingly. Thank you.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	29 Oct 2020 11:05:33
	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:36:20

US3632154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:29:02
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Nov 2020 20:56:30
User entered '22 Oct 2020' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:56:30
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Nov 2020 20:56:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:16:04
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:36:20

US3632154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:29:02
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Nov 2020 20:56:30
User entered 'Urine (URINE)' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:56:30
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Nov 2020 20:56:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:16:04
User entered 'Urine (URINE)'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:36:20

US3632154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:29:02
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Nov 2020 20:56:30
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:56:30
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Nov 2020 20:56:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:16:04
User entered 'Negative (NEGATIVE)'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:36:20

US3632154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Per CDM:Kindly consider to update the response as Yes/No.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 12:24:29
Query 'Per CDM:Kindly consider to update the response as Yes/No.Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 13:38:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 13:38:14
User opened query 'Per CDM:Kindly consider to update the response as Yes/No.Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 05:19:08
User entered empty.	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:36:20

US3632154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:16:04
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:36:20

US3632154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:16:04
User entered '13:54'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:36:20

US3632154

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	29 Oct 2020 18:16:04
User entered '22 Oct 2020 13:54'	System	22 Oct 2020 20:36:20

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '15:08'	Sarah Wiatrek (b) (4)	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '22 Oct 2020 15:08'	System	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Left Arm (LEFT ARM)'	Sarah Wiatrek (b) (4)	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'ONCE'	System	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 19:13:35

US3632154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:58

US3632154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:58

US3632154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '14:33' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	22 Oct 2020 20:20:33
User entered '14:50'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:19:58

US3632154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '22 Oct 2020 14:33'	System	22 Oct 2020 20:20:33
User entered '22 Oct 2020 14:50'	System	22 Oct 2020 20:19:58

US3632154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:55:49

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '22 Oct 2020'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:20:23

US3632154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:20:23

US3632154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:20:23

US3632154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '14:50'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:20:23

US3632154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '22 Oct 2020 14:50'	System	22 Oct 2020 20:20:23

US3632154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sarah Wiatrek (b) (4) (b) (4)	22 Oct 2020 20:20:23

US3632154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:20:23

US3632154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	22 Oct 2020 20:20:23

US3632154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	22 Oct 2020 20:20:23

US3632154

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	22 Oct 2020 20:21:27

US3632154

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'I'	System	22 Oct 2020 20:21:27

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:41:04', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '87a492f4-c050-42f0-898e-780e99ee54e9'	System	22 Oct 2020 19:41:28
User entered 'Yes (Y)'	System	22 Oct 2020 19:41:28

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:41:11', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '87a492f4-c050-42f0-898e-780e99ee54e9'	System	22 Oct 2020 19:41:28
User entered '97.4'	System	22 Oct 2020 19:41:28

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:41:18', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '87a492f4-c050-42f0-898e-780e99ee54e9'	System	22 Oct 2020 19:41:28
User entered 'No (N)'	System	22 Oct 2020 19:41:28

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:41:24', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '87a492f4-c050-42f0-898e-780e99ee54e9'	System	22 Oct 2020 19:41:28
User entered '22 Oct 2020 15:41'	System	22 Oct 2020 19:41:28

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Oct 2020 15:28'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Oct 2020 17:58'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:24:59', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '36d456f4-7e88-4654-8ea5-97e61bcc7918'	System	23 Oct 2020 05:25:20
User entered 'Yes (Y)'	System	23 Oct 2020 05:25:20

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:07', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '36d456f4-7e88-4654-8ea5-97e61bcc7918'	System	23 Oct 2020 05:25:20
User entered '98.0'	System	23 Oct 2020 05:25:20

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:12', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '36d456f4-7e88-4654-8ea5-97e61bcc7918'	System	23 Oct 2020 05:25:20
User entered 'No (N)'	System	23 Oct 2020 05:25:20

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:17', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '36d456f4-7e88-4654-8ea5-97e61bcc7918'	System	23 Oct 2020 05:25:20
User entered '23 Oct 2020 01:25'	System	23 Oct 2020 05:25:20

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Oct 2020 18:53'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 2'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:42:14', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1c2ddad9-e0d8-4118-b06a-09382acf43d2'	System	24 Oct 2020 03:42:37
User entered 'Yes (Y)'	System	24 Oct 2020 03:42:37

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:42:21', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1c2ddad9-e0d8-4118-b06a-09382acf43d2'	System	24 Oct 2020 03:42:37
User entered '98.2'	System	24 Oct 2020 03:42:37

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:42:27', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1c2ddad9-e0d8-4118-b06a-09382acf43d2'	System	24 Oct 2020 03:42:37
User entered 'No (N)'	System	24 Oct 2020 03:42:37

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:42:32', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1c2ddad9-e0d8-4118-b06a-09382acf43d2'	System	24 Oct 2020 03:42:37
User entered '23 Oct 2020 23:42'	System	24 Oct 2020 03:42:37

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 3'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 4'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:26:29', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '318fa38b-faf8-486f-b10f-73f619bd0686'	System	25 Oct 2020 22:26:47
User entered 'Yes (Y)'	System	25 Oct 2020 22:26:47

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:26:35', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '318fa38b-faf8-486f-b10f-73f619bd0686'	System	25 Oct 2020 22:26:47
User entered '97.6'	System	25 Oct 2020 22:26:47

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:26:38', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '318fa38b-faf8-486f-b10f-73f619bd0686'	System	25 Oct 2020 22:26:47
User entered 'No (N)'	System	25 Oct 2020 22:26:47

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:26:43', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '318fa38b-faf8-486f-b10f-73f619bd0686'	System	25 Oct 2020 22:26:47
User entered '25 Oct 2020 18:26'	System	25 Oct 2020 22:26:47

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 5'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:25:42', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '92f02ab9-7615-4723-a62a-8cdc24b2d162'	System	27 Oct 2020 01:26:07
User entered 'Yes (Y)'	System	27 Oct 2020 01:26:07

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:25:51', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '92f02ab9-7615-4723-a62a-8cdc24b2d162'	System	27 Oct 2020 01:26:07
User entered '97.3'	System	27 Oct 2020 01:26:07

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:25:54', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '92f02ab9-7615-4723-a62a-8cdc24b2d162'	System	27 Oct 2020 01:26:07
User entered 'No (N)'	System	27 Oct 2020 01:26:07

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:25:58', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '92f02ab9-7615-4723-a62a-8cdc24b2d162'	System	27 Oct 2020 01:26:07
User entered '26 Oct 2020 21:25'	System	27 Oct 2020 01:26:07

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 6'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:17', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6ea400c9-653b-4969-b193-c98f349af7c8'	System	28 Oct 2020 04:31:38
User entered 'Yes (Y)'	System	28 Oct 2020 04:31:38

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:26', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6ea400c9-653b-4969-b193-c98f349af7c8'	System	28 Oct 2020 04:31:38
User entered '98.4'	System	28 Oct 2020 04:31:38

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:30', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6ea400c9-653b-4969-b193-c98f349af7c8'	System	28 Oct 2020 04:31:38
User entered 'No (N)'	System	28 Oct 2020 04:31:38

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:32', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6ea400c9-653b-4969-b193-c98f349af7c8'	System	28 Oct 2020 04:31:38
User entered '28 Oct 2020 00:31'	System	28 Oct 2020 04:31:38

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 7'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:01:23', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'ae9dcc5c-c7e9-4ae1-b7d4-088d80fb9707'	System	29 Oct 2020 15:01:53
User entered 'Yes (Y)'	System	29 Oct 2020 15:01:53

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:01:39', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'ae9dcc5c-c7e9-4ae1-b7d4-088d80fb9707'	System	29 Oct 2020 15:01:53
User entered '97.8'	System	29 Oct 2020 15:01:53

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:01:42', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'ae9dcc5c-c7e9-4ae1-b7d4-088d80fb9707'	System	29 Oct 2020 15:01:53
User entered 'No (N)'	System	29 Oct 2020 15:01:53

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:01:47', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'ae9dcc5c-c7e9-4ae1-b7d4-088d80fb9707'	System	29 Oct 2020 15:01:53
User entered '29 Oct 2020 11:01'	System	29 Oct 2020 15:01:53

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:41:31', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'be171cc2-c9ba-4ff9-8cb9-3921f0e46733'	System	22 Oct 2020 19:42:12
User entered 'None (1)'	System	22 Oct 2020 19:42:12

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:41:41', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'be171cc2-c9ba-4ff9-8cb9-3921f0e46733'	System	22 Oct 2020 19:42:12
User entered 'No (N)'	System	22 Oct 2020 19:42:12

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:41:45', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'be171cc2-c9ba-4ff9-8cb9-3921f0e46733'	System	22 Oct 2020 19:42:12
User entered 'No (N)'	System	22 Oct 2020 19:42:12

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:41:55', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'be171cc2-c9ba-4ff9-8cb9-3921f0e46733'	System	22 Oct 2020 19:42:12
User entered 'None (1)'	System	22 Oct 2020 19:42:12

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:42:09', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'be171cc2-c9ba-4ff9-8cb9-3921f0e46733'	System	22 Oct 2020 19:42:12
User entered '22 Oct 2020 15:42'	System	22 Oct 2020 19:42:12

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Oct 2020 15:28'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Oct 2020 17:58'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:26', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1b218e97-7263-4cbb-ad23-249deb9e1609'	System	23 Oct 2020 05:25:44
User entered 'None (1)'	System	23 Oct 2020 05:25:44

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:30', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1b218e97-7263-4cbb-ad23-249deb9e1609'	System	23 Oct 2020 05:25:44
User entered 'No (N)'	System	23 Oct 2020 05:25:44

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:33', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1b218e97-7263-4cbb-ad23-249deb9e1609'	System	23 Oct 2020 05:25:44
User entered 'No (N)'	System	23 Oct 2020 05:25:44

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:38', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1b218e97-7263-4cbb-ad23-249deb9e1609'	System	23 Oct 2020 05:25:44
User entered 'None (1)'	System	23 Oct 2020 05:25:44

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:41', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1b218e97-7263-4cbb-ad23-249deb9e1609'	System	23 Oct 2020 05:25:44
User entered '23 Oct 2020 01:25'	System	23 Oct 2020 05:25:44

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Oct 2020 18:53'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 2'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:42:43', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '388d9703-550d-4d5b-a58f-b22baa759582'	System	24 Oct 2020 03:43:24
User entered 'None (1)'	System	24 Oct 2020 03:43:24

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:10', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '388d9703-550d-4d5b-a58f-b22baa759582'	System	24 Oct 2020 03:43:24
User entered 'No (N)'	System	24 Oct 2020 03:43:24

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:12', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '388d9703-550d-4d5b-a58f-b22baa759582'	System	24 Oct 2020 03:43:24
User entered 'No (N)'	System	24 Oct 2020 03:43:24

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:15', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '388d9703-550d-4d5b-a58f-b22baa759582'	System	24 Oct 2020 03:43:24
User entered 'None (1)'	System	24 Oct 2020 03:43:24

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:18', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '388d9703-550d-4d5b-a58f-b22baa759582'	System	24 Oct 2020 03:43:24
User entered '23 Oct 2020 23:43'	System	24 Oct 2020 03:43:24

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 3'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 4'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:26:47', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '7bd8db66-b7d6-4f61-8441-07408c6bf871'	System	25 Oct 2020 22:27:04
User entered 'None (1)'	System	25 Oct 2020 22:27:04

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:26:49', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '7bd8db66-b7d6-4f61-8441-07408c6bf871'	System	25 Oct 2020 22:27:04
User entered 'No (N)'	System	25 Oct 2020 22:27:04

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:26:52', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '7bd8db66-b7d6-4f61-8441-07408c6bf871'	System	25 Oct 2020 22:27:04
User entered 'No (N)'	System	25 Oct 2020 22:27:04

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:26:55', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '7bd8db66-b7d6-4f61-8441-07408c6bf871'	System	25 Oct 2020 22:27:04
User entered 'None (1)'	System	25 Oct 2020 22:27:04

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:26:57', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '7bd8db66-b7d6-4f61-8441-07408c6bf871'	System	25 Oct 2020 22:27:04
User entered '25 Oct 2020 18:26'	System	25 Oct 2020 22:27:04

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 5'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:02', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '53351d78-c9e3-419e-9971-112ead37ab80'	System	27 Oct 2020 01:26:22
User entered 'None (1)'	System	27 Oct 2020 01:26:22

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:06', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '53351d78-c9e3-419e-9971-112ead37ab80'	System	27 Oct 2020 01:26:22
User entered 'No (N)'	System	27 Oct 2020 01:26:22

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:09', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '53351d78-c9e3-419e-9971-112ead37ab80'	System	27 Oct 2020 01:26:22
User entered 'No (N)'	System	27 Oct 2020 01:26:22

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:11', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '53351d78-c9e3-419e-9971-112ead37ab80'	System	27 Oct 2020 01:26:22
User entered 'None (1)'	System	27 Oct 2020 01:26:22

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:14', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '53351d78-c9e3-419e-9971-112ead37ab80'	System	27 Oct 2020 01:26:22
User entered '26 Oct 2020 21:26'	System	27 Oct 2020 01:26:22

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 6'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:37', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'da9ff093-0da1-4585-b2b1-68df5409e903'	System	28 Oct 2020 04:31:54
User entered 'None (1)'	System	28 Oct 2020 04:31:54

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:40', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'da9ff093-0da1-4585-b2b1-68df5409e903'	System	28 Oct 2020 04:31:54
User entered 'No (N)'	System	28 Oct 2020 04:31:54

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:42', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'da9ff093-0da1-4585-b2b1-68df5409e903'	System	28 Oct 2020 04:31:54
User entered 'No (N)'	System	28 Oct 2020 04:31:54

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:45', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'da9ff093-0da1-4585-b2b1-68df5409e903'	System	28 Oct 2020 04:31:54
User entered 'None (1)'	System	28 Oct 2020 04:31:54

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:48', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'da9ff093-0da1-4585-b2b1-68df5409e903'	System	28 Oct 2020 04:31:54
User entered '28 Oct 2020 00:31'	System	28 Oct 2020 04:31:54

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 7'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:01:52', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'dab691fb-3ed7-4a10-bd2a-29bb7c842728'	System	29 Oct 2020 15:02:15
User entered 'None (1)'	System	29 Oct 2020 15:02:15

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:01:55', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'dab691fb-3ed7-4a10-bd2a-29bb7c842728'	System	29 Oct 2020 15:02:15
User entered 'No (N)'	System	29 Oct 2020 15:02:15

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:01:56', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'dab691fb-3ed7-4a10-bd2a-29bb7c842728'	System	29 Oct 2020 15:02:15
User entered 'No (N)'	System	29 Oct 2020 15:02:15

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:01:59', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'dab691fb-3ed7-4a10-bd2a-29bb7c842728'	System	29 Oct 2020 15:02:15
User entered 'None (1)'	System	29 Oct 2020 15:02:15

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:02:10', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'dab691fb-3ed7-4a10-bd2a-29bb7c842728'	System	29 Oct 2020 15:02:15
User entered '29 Oct 2020 11:02'	System	29 Oct 2020 15:02:15

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:42:17', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6b6a5ad1-49c0-45d6-824d-444de75c2d60'	System	22 Oct 2020 19:42:46
User entered 'None (0)'	System	22 Oct 2020 19:42:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:42:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6b6a5ad1-49c0-45d6-824d-444de75c2d60'	System	22 Oct 2020 19:42:46
User entered 'None (0)'	System	22 Oct 2020 19:42:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:42:23', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6b6a5ad1-49c0-45d6-824d-444de75c2d60'	System	22 Oct 2020 19:42:46
User entered 'None (0)'	System	22 Oct 2020 19:42:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:42:25', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6b6a5ad1-49c0-45d6-824d-444de75c2d60'	System	22 Oct 2020 19:42:46
User entered 'None (0)'	System	22 Oct 2020 19:42:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:42:27', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6b6a5ad1-49c0-45d6-824d-444de75c2d60'	System	22 Oct 2020 19:42:46
User entered 'None (0)'	System	22 Oct 2020 19:42:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:42:29', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6b6a5ad1-49c0-45d6-824d-444de75c2d60'	System	22 Oct 2020 19:42:46
User entered 'None (0)'	System	22 Oct 2020 19:42:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:42:35', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6b6a5ad1-49c0-45d6-824d-444de75c2d60'	System	22 Oct 2020 19:42:46
User entered 'No (N)'	System	22 Oct 2020 19:42:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-22T15:42:42', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6b6a5ad1-49c0-45d6-824d-444de75c2d60'	System	22 Oct 2020 19:42:46
User entered '22 Oct 2020 15:42'	System	22 Oct 2020 19:42:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Oct 2020 15:28'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Oct 2020 17:58'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:46', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '67742479-b520-490a-90e8-ca8cb1a26db5'	System	23 Oct 2020 05:26:13
User entered 'None (0)'	System	23 Oct 2020 05:26:13

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:49', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '67742479-b520-490a-90e8-ca8cb1a26db5'	System	23 Oct 2020 05:26:13
User entered 'None (0)'	System	23 Oct 2020 05:26:13

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:51', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '67742479-b520-490a-90e8-ca8cb1a26db5' User entered 'None (0)'	System	23 Oct 2020 05:26:13
	System	23 Oct 2020 05:26:13

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:56', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '67742479-b520-490a-90e8-ca8cb1a26db5' User entered 'None (0)'	System	23 Oct 2020 05:26:13
	System	23 Oct 2020 05:26:13

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:25:58', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '67742479-b520-490a-90e8-ca8cb1a26db5' User entered 'None (0)'	System	23 Oct 2020 05:26:13
	System	23 Oct 2020 05:26:13

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:26:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '67742479-b520-490a-90e8-ca8cb1a26db5'	System	23 Oct 2020 05:26:13
User entered 'None (0)'	System	23 Oct 2020 05:26:13

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:26:05', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '67742479-b520-490a-90e8-ca8cb1a26db5'	System	23 Oct 2020 05:26:13
User entered 'No (N)'	System	23 Oct 2020 05:26:13

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T01:26:08', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '67742479-b520-490a-90e8-ca8cb1a26db5'	System	23 Oct 2020 05:26:13
User entered '23 Oct 2020 01:26'	System	23 Oct 2020 05:26:13

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Oct 2020 18:53'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 2'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:23', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '4a16a3f2-444d-447f-be53-49db49538e39'	System	24 Oct 2020 03:43:45
User entered 'None (0)'	System	24 Oct 2020 03:43:45

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:24', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '4a16a3f2-444d-447f-be53-49db49538e39'	System	24 Oct 2020 03:43:45
User entered 'None (0)'	System	24 Oct 2020 03:43:45

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:27', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '4a16a3f2-444d-447f-be53-49db49538e39'	System	24 Oct 2020 03:43:45
User entered 'None (0)'	System	24 Oct 2020 03:43:45

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:29', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '4a16a3f2-444d-447f-be53-49db49538e39'	System	24 Oct 2020 03:43:45
User entered 'None (0)'	System	24 Oct 2020 03:43:45

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:31', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '4a16a3f2-444d-447f-be53-49db49538e39'	System	24 Oct 2020 03:43:45
User entered 'None (0)'	System	24 Oct 2020 03:43:45

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:33', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '4a16a3f2-444d-447f-be53-49db49538e39'	System	24 Oct 2020 03:43:45
User entered 'None (0)'	System	24 Oct 2020 03:43:45

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:38', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '4a16a3f2-444d-447f-be53-49db49538e39'	System	24 Oct 2020 03:43:45
User entered 'No (N)'	System	24 Oct 2020 03:43:45

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-23T23:43:42', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '4a16a3f2-444d-447f-be53-49db49538e39'	System	24 Oct 2020 03:43:45
User entered '23 Oct 2020 23:43'	System	24 Oct 2020 03:43:45

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 3'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 4'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:27:01', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5d688f60-d6f1-4cfc-9b1d-6bbd2a34c899'	System	25 Oct 2020 22:27:23
User entered 'None (0)'	System	25 Oct 2020 22:27:23

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:27:03', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5d688f60-d6f1-4cfc-9b1d-6bbd2a34c899'	System	25 Oct 2020 22:27:23
User entered 'None (0)'	System	25 Oct 2020 22:27:23

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:27:04', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5d688f60-d6f1-4cfc-9b1d-6bbd2a34c899'	System	25 Oct 2020 22:27:23
User entered 'None (0)'	System	25 Oct 2020 22:27:23

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:27:06', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5d688f60-d6f1-4cfc-9b1d-6bbd2a34c899'	System	25 Oct 2020 22:27:23
User entered 'None (0)'	System	25 Oct 2020 22:27:23

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:27:08', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5d688f60-d6f1-4cfc-9b1d-6bbd2a34c899'	System	25 Oct 2020 22:27:23
User entered 'None (0)'	System	25 Oct 2020 22:27:23

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:27:09', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5d688f60-d6f1-4cfc-9b1d-6bbd2a34c899'	System	25 Oct 2020 22:27:23
User entered 'None (0)'	System	25 Oct 2020 22:27:23

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:27:16', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5d688f60-d6f1-4cfc-9b1d-6bbd2a34c899'	System	25 Oct 2020 22:27:23
User entered 'No (N)'	System	25 Oct 2020 22:27:23

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-25T18:27:19', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5d688f60-d6f1-4cfc-9b1d-6bbd2a34c899'	System	25 Oct 2020 22:27:23
User entered '25 Oct 2020 18:27'	System	25 Oct 2020 22:27:23

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 5'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:17', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c4b5d6b9-fb97-4cf7-806c-83d1f9e719f1'	System	27 Oct 2020 01:26:46
User entered 'None (0)'	System	27 Oct 2020 01:26:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:19', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c4b5d6b9-fb97-4cf7-806c-83d1f9e719f1'	System	27 Oct 2020 01:26:46
User entered 'None (0)'	System	27 Oct 2020 01:26:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:21', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c4b5d6b9-fb97-4cf7-806c-83d1f9e719f1'	System	27 Oct 2020 01:26:46
User entered 'None (0)'	System	27 Oct 2020 01:26:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:24', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c4b5d6b9-fb97-4cf7-806c-83d1f9e719f1'	System	27 Oct 2020 01:26:46
User entered 'None (0)'	System	27 Oct 2020 01:26:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:26', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c4b5d6b9-fb97-4cf7-806c-83d1f9e719f1'	System	27 Oct 2020 01:26:46
User entered 'None (0)'	System	27 Oct 2020 01:26:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:28', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c4b5d6b9-fb97-4cf7-806c-83d1f9e719f1'	System	27 Oct 2020 01:26:46
User entered 'None (0)'	System	27 Oct 2020 01:26:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:30', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c4b5d6b9-fb97-4cf7-806c-83d1f9e719f1'	System	27 Oct 2020 01:26:46
User entered 'No (N)'	System	27 Oct 2020 01:26:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-26T21:26:42', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c4b5d6b9-fb97-4cf7-806c-83d1f9e719f1'	System	27 Oct 2020 01:26:46
User entered '26 Oct 2020 21:26'	System	27 Oct 2020 01:26:46

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 6'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:52', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1fd682ff-8946-4184-ad15-13783e47e079'	System	28 Oct 2020 04:32:12
User entered 'None (0)'	System	28 Oct 2020 04:32:12

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:54', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1fd682ff-8946-4184-ad15-13783e47e079'	System	28 Oct 2020 04:32:12
User entered 'None (0)'	System	28 Oct 2020 04:32:12

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:57', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1fd682ff-8946-4184-ad15-13783e47e079'	System	28 Oct 2020 04:32:12
User entered 'None (0)'	System	28 Oct 2020 04:32:12

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:31:59', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1fd682ff-8946-4184-ad15-13783e47e079'	System	28 Oct 2020 04:32:12
User entered 'None (0)'	System	28 Oct 2020 04:32:12

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:32:01', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1fd682ff-8946-4184-ad15-13783e47e079'	System	28 Oct 2020 04:32:12
User entered 'None (0)'	System	28 Oct 2020 04:32:12

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:32:03', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1fd682ff-8946-4184-ad15-13783e47e079'	System	28 Oct 2020 04:32:12
User entered 'None (0)'	System	28 Oct 2020 04:32:12

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:32:05', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1fd682ff-8946-4184-ad15-13783e47e079'	System	28 Oct 2020 04:32:12
User entered 'No (N)'	System	28 Oct 2020 04:32:12

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-28T00:32:08', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1fd682ff-8946-4184-ad15-13783e47e079'	System	28 Oct 2020 04:32:12
User entered '28 Oct 2020 00:32'	System	28 Oct 2020 04:32:12

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	22 Oct 2020 19:13:35
User entered 'Day 7'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:02:15', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '682f321d-c6a2-4a0e-bc9d-58a9e6dfd868'	System	29 Oct 2020 15:02:38
User entered 'None (0)'	System	29 Oct 2020 15:02:38

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:02:18', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '682f321d-c6a2-4a0e-bc9d-58a9e6dfd868'	System	29 Oct 2020 15:02:38
User entered 'None (0)'	System	29 Oct 2020 15:02:38

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:02:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '682f321d-c6a2-4a0e-bc9d-58a9e6dfd868'	System	29 Oct 2020 15:02:38
User entered 'None (0)'	System	29 Oct 2020 15:02:38

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:02:21', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '682f321d-c6a2-4a0e-bc9d-58a9e6dfd868'	System	29 Oct 2020 15:02:38
User entered 'None (0)'	System	29 Oct 2020 15:02:38

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:02:23', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '682f321d-c6a2-4a0e-bc9d-58a9e6dfd868'	System	29 Oct 2020 15:02:38
User entered 'None (0)'	System	29 Oct 2020 15:02:38

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:02:25', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '682f321d-c6a2-4a0e-bc9d-58a9e6dfd868'	System	29 Oct 2020 15:02:38
User entered 'None (0)'	System	29 Oct 2020 15:02:38

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:02:26', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '682f321d-c6a2-4a0e-bc9d-58a9e6dfd868'	System	29 Oct 2020 15:02:38
User entered 'No (N)'	System	29 Oct 2020 15:02:38

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-10-29T11:02:29', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '682f321d-c6a2-4a0e-bc9d-58a9e6dfd868'	System	29 Oct 2020 15:02:38
User entered '29 Oct 2020 11:02'	System	29 Oct 2020 15:02:38

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 19:13:35

US3632154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 19:13:35

US3632154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	29 Oct 2020 20:36:23

US3632154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '29 Oct 2020'	Sarah Wiatrek (b) (4)	29 Oct 2020 20:36:23

US3632154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Contact Made (CONTACT MADE)'	Sarah Wiatrek (b) (4)	29 Oct 2020 20:36:23

US3632154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Sarah Wiatrek (b) (4)	29 Oct 2020 20:36:23

US3632154

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Sarah Wiatrek (b) (4)	29 Oct 2020 20:36:28

US3632154

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'I'	System	29 Oct 2020 20:36:28

US3632154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:41:02

US3632154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:41:02

US3632154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 15:41:02

US3632154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:41:02

US3632154

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:41:35

US3632154

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'I'	System	05 Nov 2020 15:41:35

US3632154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Nov 2020 15:04:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 15:04:40
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 15:04:40
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 13:41:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 13:41:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 13:41:16

US3632154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '12 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 15:04:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 13:41:33
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 13:41:16

US3632154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 13:41:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Nov 2020 13:41:16

US3632154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 13:41:16

US3632154

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 15:04:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 15:04:45
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 13:41:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 13:41:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 13:41:18

US3632154

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '1'	System	12 Nov 2020 15:04:45
User entered empty.	System	12 Nov 2020 13:41:39
User entered '1'	System	12 Nov 2020 13:41:18

US3632154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:19:24
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '19 Nov 2020'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:19:24
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Clinic (Clinic)'	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:19:24

US3632154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'VISIT2'	System	19 Nov 2020 21:19:24

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User accepted default value 'Pre-Dose (PREDOSE)'	Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '19 Nov 2020'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '14:58'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '19 Nov 2020 14:58'	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '97.4' F	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Oral (Oral)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '88'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'bpm'	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '24'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'breaths/min'	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '101'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'mmHg'	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '63'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'mmHg'	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User accepted default value 'Post-Dose (POSTDOSE)'	Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 22:01:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:01:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:01:26
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:47:27
User entered empty.	Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '19 Nov 2020' reason for change: Data Entry Error	Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:01:26
User entered empty.	Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '16:52' reason for change: Data Entry Error	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:01:26
User entered empty.	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '19 Nov 2020 16:52'	System	19 Nov 2020 22:01:26
User entered empty.	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '98.1' F reason for change: Data Entry Error	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:01:26
User entered empty.	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Oral (Oral)' reason for change: Data Entry Error	Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:01:26
User entered empty.	Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:47:27
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '83' reason for change: Data Entry Error	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:01:26
User entered empty.	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'bpm'	System	19 Nov 2020 22:01:26
User entered empty.	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '24' reason for change: Data Entry Error	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:01:26
User entered empty.	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'breaths/min'	System	19 Nov 2020 22:01:26
User entered empty.	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '125' reason for change: Data Entry Error	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:01:26
User entered empty.	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'mmHg'	System	19 Nov 2020 22:01:26
User entered empty.	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '77' reason for change: Data Entry Error	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:01:26
User entered empty.	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'mmHg'	System	19 Nov 2020 22:01:26
User entered empty.	System	19 Nov 2020 21:47:27

US3632154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:46:42
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '19 Nov 2020'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:46:42
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:48:25
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '19 Nov 2020'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:48:25
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Urine (URINE)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:48:25
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Negative (NEGATIVE)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:48:25
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:48:25
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:42:09
User entered '19 Nov 2020'	Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:48:25

US3632154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 13:42:09
User entered '13:48'	Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:48:25

US3632154

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	23 Nov 2020 13:42:09
User entered '19 Nov 2020 13:48'	System	19 Nov 2020 21:48:25

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:02
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:02
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:02
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'MRNA-1273 OR PLACEBO'	System	19 Nov 2020 21:49:02

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '19 Nov 2020'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:02
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '16:20'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:02
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '19 Nov 2020 16:20'	System	19 Nov 2020 21:49:02

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:49:02

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'ONCE'	System	19 Nov 2020 21:49:02

US3632154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'INTRAMUSCULAR'	System	19 Nov 2020 21:49:02

US3632154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:19:43
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:19:43
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:19:43
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	19 Nov 2020 21:19:43

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:55:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '19 Nov 2020'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:41
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:49:41

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:41
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '16:09'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:41
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '19 Nov 2020 16:09'	System	19 Nov 2020 21:49:41

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bezuayehu Mandefro (b) (4)	19 Nov 2020 21:49:41

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:41
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 21:49:41
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	19 Nov 2020 21:49:41

US3632154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:01:34
	(b) (4)	

US3632154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '1'	System	19 Nov 2020 22:01:34

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:54:17', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '0289396c-a381-4a91-8c24-e44cd8aa7841'	System	19 Nov 2020 21:55:15
User entered 'Yes (Y)'	System	19 Nov 2020 21:55:15

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:55:04', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '0289396c-a381-4a91-8c24-e44cd8aa7841'	System	19 Nov 2020 21:55:15
User entered '98.1'	System	19 Nov 2020 21:55:15

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:55:08', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '0289396c-a381-4a91-8c24-e44cd8aa7841'	System	19 Nov 2020 21:55:15
User entered 'No (N)'	System	19 Nov 2020 21:55:15

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:55:11', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '0289396c-a381-4a91-8c24-e44cd8aa7841'	System	19 Nov 2020 21:55:15
User entered '19 Nov 2020 16:55'	System	19 Nov 2020 21:55:15

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '19 Nov 2020 16:40'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '19 Nov 2020 19:10'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:45:43', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'fafb8073-ead2-4db8-8f05-81414d5a6e6d'	System	20 Nov 2020 05:49:00
User entered 'Yes (Y)'	System	20 Nov 2020 05:49:00

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:48:50', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'fafb8073-ead2-4db8-8f05-81414d5a6e6d'	System	20 Nov 2020 05:49:00
User entered '98.0'	System	20 Nov 2020 05:49:00

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:48:53', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'fafb8073-ead2-4db8-8f05-81414d5a6e6d'	System	20 Nov 2020 05:49:00
User entered 'No (N)'	System	20 Nov 2020 05:49:00

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:48:56', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'fafb8073-ead2-4db8-8f05-81414d5a6e6d'	System	20 Nov 2020 05:49:00
User entered '20 Nov 2020 00:48'	System	20 Nov 2020 05:49:00

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '19 Nov 2020 20:05'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 2'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:55:32', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '2f302246-df0b-4db1-91f6-26948987ed39'	System	21 Nov 2020 00:58:10
User entered 'Yes (Y)'	System	21 Nov 2020 00:58:10

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:57:54', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '2f302246-df0b-4db1-91f6-26948987ed39'	System	21 Nov 2020 00:58:10
User entered '98.9'	System	21 Nov 2020 00:58:10

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '2f302246-df0b-4db1-91f6-26948987ed39'	System	21 Nov 2020 00:58:10
User entered 'No (N)'	System	21 Nov 2020 00:58:10

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:06', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '2f302246-df0b-4db1-91f6-26948987ed39'	System	21 Nov 2020 00:58:10
User entered '20 Nov 2020 19:58'	System	21 Nov 2020 00:58:10

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 3'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:35:47', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '862cb04e-3e8a-47b9-b240-97f33a524a3f'	System	22 Nov 2020 02:38:00
User entered 'Yes (Y)'	System	22 Nov 2020 02:38:00

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:37:50', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '862cb04e-3e8a-47b9-b240-97f33a524a3f'	System	22 Nov 2020 02:38:00
User entered '97.5'	System	22 Nov 2020 02:38:00

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:37:54', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '862cb04e-3e8a-47b9-b240-97f33a524a3f'	System	22 Nov 2020 02:38:00
User entered 'No (N)'	System	22 Nov 2020 02:38:00

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:37:58', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '862cb04e-3e8a-47b9-b240-97f33a524a3f'	System	22 Nov 2020 02:38:00
User entered '21 Nov 2020 21:37'	System	22 Nov 2020 02:38:00

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 4'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:20:36', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '18a708bc-f17f-48de-96cc-62fd8d5e569c'	System	22 Nov 2020 21:22:01
User entered 'Yes (Y)'	System	22 Nov 2020 21:22:01

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:21:51', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '18a708bc-f17f-48de-96cc-62fd8d5e569c'	System	22 Nov 2020 21:22:01
User entered '98.3'	System	22 Nov 2020 21:22:01

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:21:55', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '18a708bc-f17f-48de-96cc-62fd8d5e569c'	System	22 Nov 2020 21:22:01
User entered 'No (N)'	System	22 Nov 2020 21:22:01

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:21:59', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '18a708bc-f17f-48de-96cc-62fd8d5e569c'	System	22 Nov 2020 21:22:01
User entered '22 Nov 2020 16:21'	System	22 Nov 2020 21:22:01

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 5'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:44:41', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b7d7b18c-f92d-46ae-a8b9-e4508eb49c17'	System	23 Nov 2020 23:44:56
User entered 'Yes (Y)'	System	23 Nov 2020 23:44:56

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:44:46', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b7d7b18c-f92d-46ae-a8b9-e4508eb49c17'	System	23 Nov 2020 23:44:56
User entered '97.6'	System	23 Nov 2020 23:44:56

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:44:49', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b7d7b18c-f92d-46ae-a8b9-e4508eb49c17'	System	23 Nov 2020 23:44:56
User entered 'No (N)'	System	23 Nov 2020 23:44:56

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:44:52', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b7d7b18c-f92d-46ae-a8b9-e4508eb49c17'	System	23 Nov 2020 23:44:56
User entered '23 Nov 2020 18:44'	System	23 Nov 2020 23:44:56

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 6'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:09', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6e8de3a5-4d12-4d92-b13f-30f15cf7a54b'	System	25 Nov 2020 01:58:29
User entered 'Yes (Y)'	System	25 Nov 2020 01:58:29

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:14', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6e8de3a5-4d12-4d92-b13f-30f15cf7a54b'	System	25 Nov 2020 01:58:29
User entered '98.6'	System	25 Nov 2020 01:58:29

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6e8de3a5-4d12-4d92-b13f-30f15cf7a54b'	System	25 Nov 2020 01:58:29
User entered 'No (N)'	System	25 Nov 2020 01:58:29

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:22', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6e8de3a5-4d12-4d92-b13f-30f15cf7a54b'	System	25 Nov 2020 01:58:29
User entered '24 Nov 2020 20:58'	System	25 Nov 2020 01:58:29

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 7'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:38:45', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '86485e30-b3f5-49ca-85c3-a42e04aae257'	System	25 Nov 2020 22:38:59
User entered 'Yes (Y)'	System	25 Nov 2020 22:38:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:38:49', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '86485e30-b3f5-49ca-85c3-a42e04aae257'	System	25 Nov 2020 22:38:59
User entered '97.0'	System	25 Nov 2020 22:38:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:38:51', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '86485e30-b3f5-49ca-85c3-a42e04aae257'	System	25 Nov 2020 22:38:59
User entered 'No (N)'	System	25 Nov 2020 22:38:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:38:55', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '86485e30-b3f5-49ca-85c3-a42e04aae257'	System	25 Nov 2020 22:38:59
User entered '25 Nov 2020 17:38'	System	25 Nov 2020 22:38:59

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:55:56', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a6457e0d-5277-423c-b29b-370753755d47'	System	19 Nov 2020 21:56:15
User entered 'None (1)'	System	19 Nov 2020 21:56:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:02', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a6457e0d-5277-423c-b29b-370753755d47'	System	19 Nov 2020 21:56:15
User entered 'No (N)'	System	19 Nov 2020 21:56:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:05', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a6457e0d-5277-423c-b29b-370753755d47'	System	19 Nov 2020 21:56:15
User entered 'No (N)'	System	19 Nov 2020 21:56:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:08', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a6457e0d-5277-423c-b29b-370753755d47'	System	19 Nov 2020 21:56:15
User entered 'None (1)'	System	19 Nov 2020 21:56:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:11', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a6457e0d-5277-423c-b29b-370753755d47'	System	19 Nov 2020 21:56:15
User entered '19 Nov 2020 16:56'	System	19 Nov 2020 21:56:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '19 Nov 2020 16:40'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '19 Nov 2020 19:10'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:01', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '76b0b5dc-e384-42e8-b759-dc7f3dd1d43b'	System	20 Nov 2020 05:49:15
User entered 'None (1)'	System	20 Nov 2020 05:49:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:04', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '76b0b5dc-e384-42e8-b759-dc7f3dd1d43b'	System	20 Nov 2020 05:49:15
User entered 'No (N)'	System	20 Nov 2020 05:49:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:06', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '76b0b5dc-e384-42e8-b759-dc7f3dd1d43b'	System	20 Nov 2020 05:49:15
User entered 'No (N)'	System	20 Nov 2020 05:49:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:08', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '76b0b5dc-e384-42e8-b759-dc7f3dd1d43b'	System	20 Nov 2020 05:49:15
User entered 'None (1)'	System	20 Nov 2020 05:49:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:11', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '76b0b5dc-e384-42e8-b759-dc7f3dd1d43b'	System	20 Nov 2020 05:49:15
User entered '20 Nov 2020 00:49'	System	20 Nov 2020 05:49:15

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '19 Nov 2020 20:05'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 2'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:15', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5a5219ce-4708-4f14-b1ee-90ddd93f63d9'	System	21 Nov 2020 00:58:38
User entered 'None (1)'	System	21 Nov 2020 00:58:38

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:19', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5a5219ce-4708-4f14-b1ee-90ddd93f63d9'	System	21 Nov 2020 00:58:38
User entered 'No (N)'	System	21 Nov 2020 00:58:38

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:28', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5a5219ce-4708-4f14-b1ee-90ddd93f63d9'	System	21 Nov 2020 00:58:38
User entered 'No (N)'	System	21 Nov 2020 00:58:38

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:30', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5a5219ce-4708-4f14-b1ee-90ddd93f63d9'	System	21 Nov 2020 00:58:38
User entered 'None (1)'	System	21 Nov 2020 00:58:38

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:35', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '5a5219ce-4708-4f14-b1ee-90ddd93f63d9'	System	21 Nov 2020 00:58:38
User entered '20 Nov 2020 19:58'	System	21 Nov 2020 00:58:38

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 3'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:03', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '676ad949-ccbf-45e8-a5e7-fc65e5066238'	System	22 Nov 2020 02:38:32
User entered 'None (1)'	System	22 Nov 2020 02:38:32

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:15', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '676ad949-ccbf-45e8-a5e7-fc65e5066238'	System	22 Nov 2020 02:38:32
User entered 'No (N)'	System	22 Nov 2020 02:38:32

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:21', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '676ad949-ccbf-45e8-a5e7-fc65e5066238'	System	22 Nov 2020 02:38:32
User entered 'No (N)'	System	22 Nov 2020 02:38:32

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:25', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '676ad949-ccbf-45e8-a5e7-fc65e5066238'	System	22 Nov 2020 02:38:32
User entered 'None (1)'	System	22 Nov 2020 02:38:32

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:29', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '676ad949-ccbf-45e8-a5e7-fc65e5066238'	System	22 Nov 2020 02:38:32
User entered '21 Nov 2020 21:38'	System	22 Nov 2020 02:38:32

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 4'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:09', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '14a43ec8-6541-4876-aa1d-39399e105830'	System	22 Nov 2020 21:22:19
User entered 'None (1)'	System	22 Nov 2020 21:22:19

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:07', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '14a43ec8-6541-4876-aa1d-39399e105830'	System	22 Nov 2020 21:22:19
User entered 'No (N)'	System	22 Nov 2020 21:22:19

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:11', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '14a43ec8-6541-4876-aa1d-39399e105830'	System	22 Nov 2020 21:22:19
User entered 'No (N)'	System	22 Nov 2020 21:22:19

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:13', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '14a43ec8-6541-4876-aa1d-39399e105830'	System	22 Nov 2020 21:22:19
User entered 'None (1)'	System	22 Nov 2020 21:22:19

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:16', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '14a43ec8-6541-4876-aa1d-39399e105830'	System	22 Nov 2020 21:22:19
User entered '22 Nov 2020 16:22'	System	22 Nov 2020 21:22:19

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 5'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:44:55', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '19039711-226b-43c4-8094-3abd211b0384'	System	23 Nov 2020 23:45:08
User entered 'None (1)'	System	23 Nov 2020 23:45:08

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:44:57', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '19039711-226b-43c4-8094-3abd211b0384'	System	23 Nov 2020 23:45:08
User entered 'No (N)'	System	23 Nov 2020 23:45:08

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:44:59', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '19039711-226b-43c4-8094-3abd211b0384'	System	23 Nov 2020 23:45:08
User entered 'No (N)'	System	23 Nov 2020 23:45:08

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '19039711-226b-43c4-8094-3abd211b0384'	System	23 Nov 2020 23:45:08
User entered 'None (1)'	System	23 Nov 2020 23:45:08

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:03', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '19039711-226b-43c4-8094-3abd211b0384'	System	23 Nov 2020 23:45:08
User entered '23 Nov 2020 18:45'	System	23 Nov 2020 23:45:08

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 6'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:27', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3477a1c4-490e-467f-8cb4-36e127e00972'	System	25 Nov 2020 01:58:40
User entered 'None (1)'	System	25 Nov 2020 01:58:40

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:30', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3477a1c4-490e-467f-8cb4-36e127e00972'	System	25 Nov 2020 01:58:40
User entered 'No (N)'	System	25 Nov 2020 01:58:40

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:32', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3477a1c4-490e-467f-8cb4-36e127e00972'	System	25 Nov 2020 01:58:40
User entered 'No (N)'	System	25 Nov 2020 01:58:40

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:35', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3477a1c4-490e-467f-8cb4-36e127e00972'	System	25 Nov 2020 01:58:40
User entered 'None (1)'	System	25 Nov 2020 01:58:40

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:38', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3477a1c4-490e-467f-8cb4-36e127e00972'	System	25 Nov 2020 01:58:40
User entered '24 Nov 2020 20:58'	System	25 Nov 2020 01:58:40

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 7'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:38:58', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '761bcbf9-2547-41c3-b8ed-e7bf403dc956'	System	25 Nov 2020 22:39:12
User entered 'None (1)'	System	25 Nov 2020 22:39:12

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:01', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '761bcbf9-2547-41c3-b8ed-e7bf403dc956'	System	25 Nov 2020 22:39:12
User entered 'No (N)'	System	25 Nov 2020 22:39:12

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:03', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '761bcbf9-2547-41c3-b8ed-e7bf403dc956'	System	25 Nov 2020 22:39:12
User entered 'No (N)'	System	25 Nov 2020 22:39:12

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:06', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '761bcbf9-2547-41c3-b8ed-e7bf403dc956'	System	25 Nov 2020 22:39:12
User entered 'None (1)'	System	25 Nov 2020 22:39:12

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:10', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '761bcbf9-2547-41c3-b8ed-e7bf403dc956'	System	25 Nov 2020 22:39:12
User entered '25 Nov 2020 17:39'	System	25 Nov 2020 22:39:12

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:15', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '46eb0426-3573-4d21-b824-47962b6fd940'	System	19 Nov 2020 21:56:33
User entered 'None (0)'	System	19 Nov 2020 21:56:33

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:16', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '46eb0426-3573-4d21-b824-47962b6fd940'	System	19 Nov 2020 21:56:33
User entered 'None (0)'	System	19 Nov 2020 21:56:33

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:18', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '46eb0426-3573-4d21-b824-47962b6fd940'	System	19 Nov 2020 21:56:33
User entered 'None (0)'	System	19 Nov 2020 21:56:33

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '46eb0426-3573-4d21-b824-47962b6fd940'	System	19 Nov 2020 21:56:33
User entered 'None (0)'	System	19 Nov 2020 21:56:33

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:21', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '46eb0426-3573-4d21-b824-47962b6fd940'	System	19 Nov 2020 21:56:33
User entered 'None (0)'	System	19 Nov 2020 21:56:33

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:23', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '46eb0426-3573-4d21-b824-47962b6fd940'	System	19 Nov 2020 21:56:33
User entered 'None (0)'	System	19 Nov 2020 21:56:33

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:25', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '46eb0426-3573-4d21-b824-47962b6fd940'	System	19 Nov 2020 21:56:33
User entered 'No (N)'	System	19 Nov 2020 21:56:33

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-19T16:56:30', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '46eb0426-3573-4d21-b824-47962b6fd940'	System	19 Nov 2020 21:56:33
User entered '19 Nov 2020 16:56'	System	19 Nov 2020 21:56:33

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '19 Nov 2020 16:40'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '19 Nov 2020 19:10'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:15', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a5d5f20e-1b9f-4c49-91fd-5151fb19a690'	System	20 Nov 2020 05:49:30
User entered 'None (0)'	System	20 Nov 2020 05:49:30

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:16', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a5d5f20e-1b9f-4c49-91fd-5151fb19a690'	System	20 Nov 2020 05:49:30
User entered 'None (0)'	System	20 Nov 2020 05:49:30

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:18', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a5d5f20e-1b9f-4c49-91fd-5151fb19a690'	System	20 Nov 2020 05:49:30
User entered 'None (0)'	System	20 Nov 2020 05:49:30

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:19', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a5d5f20e-1b9f-4c49-91fd-5151fb19a690'	System	20 Nov 2020 05:49:30
User entered 'None (0)'	System	20 Nov 2020 05:49:30

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a5d5f20e-1b9f-4c49-91fd-5151fb19a690'	System	20 Nov 2020 05:49:30
User entered 'None (0)'	System	20 Nov 2020 05:49:30

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:21', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a5d5f20e-1b9f-4c49-91fd-5151fb19a690'	System	20 Nov 2020 05:49:30
User entered 'None (0)'	System	20 Nov 2020 05:49:30

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:23', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a5d5f20e-1b9f-4c49-91fd-5151fb19a690'	System	20 Nov 2020 05:49:30
User entered 'No (N)'	System	20 Nov 2020 05:49:30

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T00:49:26', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'a5d5f20e-1b9f-4c49-91fd-5151fb19a690'	System	20 Nov 2020 05:49:30
User entered '20 Nov 2020 00:49'	System	20 Nov 2020 05:49:30

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '19 Nov 2020 20:05'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 2'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:38', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bf1aea82-0f6a-4239-ac42-3b6d58ff3756'	System	21 Nov 2020 00:59:24
User entered 'None (0)'	System	21 Nov 2020 00:59:24

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:40', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bf1aea82-0f6a-4239-ac42-3b6d58ff3756'	System	21 Nov 2020 00:59:24
User entered 'None (0)'	System	21 Nov 2020 00:59:24

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:42', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bf1aea82-0f6a-4239-ac42-3b6d58ff3756'	System	21 Nov 2020 00:59:24
User entered 'None (0)'	System	21 Nov 2020 00:59:24

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:46', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bf1aea82-0f6a-4239-ac42-3b6d58ff3756'	System	21 Nov 2020 00:59:24
User entered 'None (0)'	System	21 Nov 2020 00:59:24

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:48', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bf1aea82-0f6a-4239-ac42-3b6d58ff3756'	System	21 Nov 2020 00:59:24
User entered 'None (0)'	System	21 Nov 2020 00:59:24

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:58:50', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bf1aea82-0f6a-4239-ac42-3b6d58ff3756'	System	21 Nov 2020 00:59:24
User entered 'None (0)'	System	21 Nov 2020 00:59:24

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:59:08', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bf1aea82-0f6a-4239-ac42-3b6d58ff3756'	System	21 Nov 2020 00:59:24
User entered 'Yes (Y)'	System	21 Nov 2020 00:59:24

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-20T19:59:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bf1aea82-0f6a-4239-ac42-3b6d58ff3756'	System	21 Nov 2020 00:59:24
User entered '20 Nov 2020 19:59'	System	21 Nov 2020 00:59:24

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 3'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:34', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '959a5ca6-4097-4383-b759-7ec24c35a2e4'	System	22 Nov 2020 02:39:06
User entered 'None (0)'	System	22 Nov 2020 02:39:06

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:36', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '959a5ca6-4097-4383-b759-7ec24c35a2e4'	System	22 Nov 2020 02:39:06
User entered 'None (0)'	System	22 Nov 2020 02:39:06

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:39', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '959a5ca6-4097-4383-b759-7ec24c35a2e4'	System	22 Nov 2020 02:39:06
User entered 'None (0)'	System	22 Nov 2020 02:39:06

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:42', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '959a5ca6-4097-4383-b759-7ec24c35a2e4'	System	22 Nov 2020 02:39:06
User entered 'None (0)'	System	22 Nov 2020 02:39:06

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:45', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '959a5ca6-4097-4383-b759-7ec24c35a2e4'	System	22 Nov 2020 02:39:06
User entered 'None (0)'	System	22 Nov 2020 02:39:06

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:46', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '959a5ca6-4097-4383-b759-7ec24c35a2e4'	System	22 Nov 2020 02:39:06
User entered 'None (0)'	System	22 Nov 2020 02:39:06

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:38:49', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '959a5ca6-4097-4383-b759-7ec24c35a2e4'	System	22 Nov 2020 02:39:06
User entered 'No (N)'	System	22 Nov 2020 02:39:06

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-21T21:39:01', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '959a5ca6-4097-4383-b759-7ec24c35a2e4'	System	22 Nov 2020 02:39:06
User entered '21 Nov 2020 21:39'	System	22 Nov 2020 02:39:06

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 4'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '125f1531-7018-413f-a38b-2a016e528fe2'	System	22 Nov 2020 21:22:37
User entered 'None (0)'	System	22 Nov 2020 21:22:37

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:21', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '125f1531-7018-413f-a38b-2a016e528fe2'	System	22 Nov 2020 21:22:37
User entered 'None (0)'	System	22 Nov 2020 21:22:37

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:23', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '125f1531-7018-413f-a38b-2a016e528fe2'	System	22 Nov 2020 21:22:37
User entered 'None (0)'	System	22 Nov 2020 21:22:37

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:25', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '125f1531-7018-413f-a38b-2a016e528fe2'	System	22 Nov 2020 21:22:37
User entered 'None (0)'	System	22 Nov 2020 21:22:37

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:27', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '125f1531-7018-413f-a38b-2a016e528fe2'	System	22 Nov 2020 21:22:37
User entered 'None (0)'	System	22 Nov 2020 21:22:37

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:28', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '125f1531-7018-413f-a38b-2a016e528fe2'	System	22 Nov 2020 21:22:37
User entered 'None (0)'	System	22 Nov 2020 21:22:37

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:30', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '125f1531-7018-413f-a38b-2a016e528fe2'	System	22 Nov 2020 21:22:37
User entered 'No (N)'	System	22 Nov 2020 21:22:37

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-22T16:22:33', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '125f1531-7018-413f-a38b-2a016e528fe2'	System	22 Nov 2020 21:22:37
User entered '22 Nov 2020 16:22'	System	22 Nov 2020 21:22:37

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 5'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:06', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cba92cde-ccc5-4e66-b105-5b4b6b120173'	System	23 Nov 2020 23:45:21
User entered 'None (0)'	System	23 Nov 2020 23:45:21

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:07', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cba92cde-ccc5-4e66-b105-5b4b6b120173'	System	23 Nov 2020 23:45:21
User entered 'None (0)'	System	23 Nov 2020 23:45:21

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:08', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cba92cde-ccc5-4e66-b105-5b4b6b120173'	System	23 Nov 2020 23:45:21
User entered 'None (0)'	System	23 Nov 2020 23:45:21

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:10', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cba92cde-ccc5-4e66-b105-5b4b6b120173'	System	23 Nov 2020 23:45:21
User entered 'None (0)'	System	23 Nov 2020 23:45:21

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:11', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cba92cde-ccc5-4e66-b105-5b4b6b120173'	System	23 Nov 2020 23:45:21
User entered 'None (0)'	System	23 Nov 2020 23:45:21

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:12', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cba92cde-ccc5-4e66-b105-5b4b6b120173'	System	23 Nov 2020 23:45:21
User entered 'None (0)'	System	23 Nov 2020 23:45:21

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:14', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cba92cde-ccc5-4e66-b105-5b4b6b120173'	System	23 Nov 2020 23:45:21
User entered 'No (N)'	System	23 Nov 2020 23:45:21

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-23T18:45:17', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cba92cde-ccc5-4e66-b105-5b4b6b120173'	System	23 Nov 2020 23:45:21
User entered '23 Nov 2020 18:45'	System	23 Nov 2020 23:45:21

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 6'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:44', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '23508310-c034-4897-9385-6e3ca1f56236'	System	25 Nov 2020 01:59:07
User entered 'None (0)'	System	25 Nov 2020 01:59:07

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:46', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '23508310-c034-4897-9385-6e3ca1f56236'	System	25 Nov 2020 01:59:07
User entered 'None (0)'	System	25 Nov 2020 01:59:07

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:49', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '23508310-c034-4897-9385-6e3ca1f56236'	System	25 Nov 2020 01:59:07
User entered 'None (0)'	System	25 Nov 2020 01:59:07

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:51', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '23508310-c034-4897-9385-6e3ca1f56236'	System	25 Nov 2020 01:59:07
User entered 'None (0)'	System	25 Nov 2020 01:59:07

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:52', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '23508310-c034-4897-9385-6e3ca1f56236'	System	25 Nov 2020 01:59:07
User entered 'None (0)'	System	25 Nov 2020 01:59:07

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:58:54', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '23508310-c034-4897-9385-6e3ca1f56236'	System	25 Nov 2020 01:59:07
User entered 'None (0)'	System	25 Nov 2020 01:59:07

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:59:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '23508310-c034-4897-9385-6e3ca1f56236'	System	25 Nov 2020 01:59:07
User entered 'No (N)'	System	25 Nov 2020 01:59:07

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-24T20:59:02', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '23508310-c034-4897-9385-6e3ca1f56236'	System	25 Nov 2020 01:59:07
User entered '24 Nov 2020 20:59'	System	25 Nov 2020 01:59:07

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
Data entry locked.	System	19 Nov 2020 21:49:02
User entered 'Day 7'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:13', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '21873d18-45b2-495d-be73-635634d2cb35'	System	25 Nov 2020 22:39:32
User entered 'None (0)'	System	25 Nov 2020 22:39:32

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:15', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '21873d18-45b2-495d-be73-635634d2cb35'	System	25 Nov 2020 22:39:32
User entered 'None (0)'	System	25 Nov 2020 22:39:32

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:16', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '21873d18-45b2-495d-be73-635634d2cb35'	System	25 Nov 2020 22:39:32
User entered 'None (0)'	System	25 Nov 2020 22:39:32

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:18', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '21873d18-45b2-495d-be73-635634d2cb35'	System	25 Nov 2020 22:39:32
User entered 'None (0)'	System	25 Nov 2020 22:39:32

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:19', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '21873d18-45b2-495d-be73-635634d2cb35'	System	25 Nov 2020 22:39:32
User entered 'None (0)'	System	25 Nov 2020 22:39:32

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '21873d18-45b2-495d-be73-635634d2cb35'	System	25 Nov 2020 22:39:32
User entered 'None (0)'	System	25 Nov 2020 22:39:32

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:24', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '21873d18-45b2-495d-be73-635634d2cb35'	System	25 Nov 2020 22:39:32
User entered 'No (N)'	System	25 Nov 2020 22:39:32

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2020-11-25T17:39:27', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '21873d18-45b2-495d-be73-635634d2cb35'	System	25 Nov 2020 22:39:32
User entered '25 Nov 2020 17:39'	System	25 Nov 2020 22:39:32

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 21:49:02

US3632154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:55:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:49:49
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 21:49:02

US3632154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Christina Bacher (b) (4)	25 Nov 2020 14:48:20

US3632154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 08:27:22
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Done early due per Moderna instruction due to Thanksgiving break. ' (Site from System).	Christina Bacher (b) (4) (b) (4)	25 Nov 2020 14:48:55
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Nov 2020 14:48:20
User entered '25 Nov 2020'	Christina Bacher (b) (4) (b) (4)	25 Nov 2020 14:48:20

US3632154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	25 Nov 2020 14:48:20

US3632154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	Christina Bacher (b) (4)	25 Nov 2020 14:48:20

US3632154

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	Christina Bacher (b) (4)	25 Nov 2020 14:49:01

US3632154

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'I'	System	25 Nov 2020 14:49:01

US3632154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	03 Dec 2020 14:43:52
	(b) (4)	

US3632154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '03 Dec 2020'	(b) (4) Bezuayehu Mandefro	03 Dec 2020 14:43:52
	(b) (4)	

US3632154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Bezuayehu Mandefro (b) (4)	03 Dec 2020 14:43:52

US3632154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) Bezuayehu Mandefro	03 Dec 2020 14:43:52
	(b) (4)	

US3632154

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro (b) (4)	03 Dec 2020 14:43:56

US3632154

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'I'	System	03 Dec 2020 14:43:56

US3632154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro	10 Dec 2020 14:36:18
	(b) (4)	

US3632154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '10 Dec 2020'	(b) (4) Bezuayehu Mandefro	10 Dec 2020 14:36:18
	(b) (4)	

US3632154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Bezuayehu Mandefro (b) (4)	10 Dec 2020 14:36:18

US3632154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'ILLNESS visit was today so contact was made but it was not a safety call.'	(b) (4) Bezuayehu Mandefro (b) (4)	10 Dec 2020 14:36:18

US3632154

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro (b) (4)	10 Dec 2020 14:36:23

US3632154

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'I'	System	10 Dec 2020 14:36:23

US3632154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	(b) (4), (b) (6)	14 Jan 2021 14:22:01

US3632154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:01

US3632154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:01

US3632154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'VISIT3'	System	14 Jan 2021 14:22:01

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	14 Jan 2021 14:22:20

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23

US3632154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23

US3632154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:29

US3632154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:29

US3632154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:22:37

US3632154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 14:22:37

US3632154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 14:22:37

US3632154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered empty.	System	14 Jan 2021 14:22:37

US3632154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 20:17:46
User entered 'No (N)'	(b) (4), (b) (6)	14 Jan 2021 14:22:45

US3632154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered '1'	System	14 Jan 2021 20:17:46
User entered empty.	System	14 Jan 2021 14:22:45

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-01-13T10:19:53', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b4672d50-3249-492e-b760-f9b4a8b6da1b'	System	13 Jan 2021 15:20:09
User entered 'No (N)'	System	13 Jan 2021 15:20:09

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-01-13T10:20:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b4672d50-3249-492e-b760-f9b4a8b6da1b'	System	13 Jan 2021 15:20:09
User entered 'No (N)'	System	13 Jan 2021 15:20:09

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-01-13T10:20:05', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b4672d50-3249-492e-b760-f9b4a8b6da1b'	System	13 Jan 2021 15:20:09
User entered '13 Jan 2021 10:20:05'	System	13 Jan 2021 15:20:09

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-01-18T20:56:32', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3db260a4-3939-4ba6-8745-92a17824703f'	System	19 Jan 2021 01:56:43
User entered 'No (N)'	System	19 Jan 2021 01:56:43

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-01-18T20:56:38', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3db260a4-3939-4ba6-8745-92a17824703f'	System	19 Jan 2021 01:56:43
User entered 'No (N)'	System	19 Jan 2021 01:56:43

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-01-18T20:56:40', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3db260a4-3939-4ba6-8745-92a17824703f' User entered '18 Jan 2021 20:56:40'	System	19 Jan 2021 01:56:43

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-01-23T10:24:14', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '871820ad-6e01-42e1-8e23-dd1404e2fd6d'	System	23 Jan 2021 15:24:25
User entered 'No (N)'	System	23 Jan 2021 15:24:25

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-01-23T10:24:17', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '871820ad-6e01-42e1-8e23-dd1404e2fd6d'	System	23 Jan 2021 15:24:25
User entered 'No (N)'	System	23 Jan 2021 15:24:25

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-01-23T10:24:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '871820ad-6e01-42e1-8e23-dd1404e2fd6d'	System	23 Jan 2021 15:24:25
User entered '23 Jan 2021 10:24:20'	System	23 Jan 2021 15:24:25

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-02-03T09:34:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6696b504-9a82-4908-aa59-80b40ab0a4eb'	System	03 Feb 2021 14:35:46
User entered 'No (N)'	System	03 Feb 2021 14:35:46

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-02-03T09:35:38', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6696b504-9a82-4908-aa59-80b40ab0a4eb'	System	03 Feb 2021 14:35:46
User entered 'No (N)'	System	03 Feb 2021 14:35:46

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-02-03T09:35:42', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '6696b504-9a82-4908-aa59-80b40ab0a4eb'	System	03 Feb 2021 14:35:46
User entered '03 Feb 2021 09:35:42'	System	03 Feb 2021 14:35:46

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-02-07T17:19:20', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '87e97364-e431-41a3-bb21-86e8a86dfc4f'	System	07 Feb 2021 22:19:38
User entered 'No (N)'	System	07 Feb 2021 22:19:38

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-02-07T17:19:29', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '87e97364-e431-41a3-bb21-86e8a86dfc4f'	System	07 Feb 2021 22:19:38
User entered 'No (N)'	System	07 Feb 2021 22:19:38

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-02-07T17:19:32', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '87e97364-e431-41a3-bb21-86e8a86dfc4f'	System	07 Feb 2021 22:19:38
User entered '07 Feb 2021 17:19:32'	System	07 Feb 2021 22:19:38

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-02-14T18:26:24', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cd0cde07-693f-4286-900e-3ba88eae6c1e'	System	14 Feb 2021 23:26:35
User entered 'No (N)'	System	14 Feb 2021 23:26:35

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-02-14T18:26:28', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cd0cde07-693f-4286-900e-3ba88eae6c1e'	System	14 Feb 2021 23:26:35
User entered 'No (N)'	System	14 Feb 2021 23:26:35

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-02-14T18:26:30', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cd0cde07-693f-4286-900e-3ba88eae6c1e'	System	14 Feb 2021 23:26:35
User entered '14 Feb 2021 18:26:30'	System	14 Feb 2021 23:26:35

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-02-24T20:54:42-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1b85cead-69d9-4ae0-aed2-b125748101bf' User entered 'No (N)'	System	25 Feb 2021 01:54:55

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-02-24T20:54:48-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1b85cead-69d9-4ae0-aed2-b125748101bf'	System	25 Feb 2021 01:54:55
User entered 'No (N)'	System	25 Feb 2021 01:54:55

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-02-24T20:54:51-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1b85cead-69d9-4ae0-aed2-b125748101bf' User entered '24 Feb 2021 20:54:51'	System	25 Feb 2021 01:54:55
	System	25 Feb 2021 01:54:55

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-02-28T21:43:50-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cd83ef3c-66ca-4c28-81b8-e033b37f865c'	System	01 Mar 2021 02:46:55
User entered 'No (N)'	System	01 Mar 2021 02:46:55

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-02-28T21:43:58-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cd83ef3c-66ca-4c28-81b8-e033b37f865c'	System	01 Mar 2021 02:46:55
User entered 'No (N)'	System	01 Mar 2021 02:46:55

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-02-28T21:44:01-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cd83ef3c-66ca-4c28-81b8-e033b37f865c'	System	01 Mar 2021 02:46:55
User entered '28 Feb 2021 21:44:01'	System	01 Mar 2021 02:46:55

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-03-07T00:30:00-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3c8186e8-43b4-4569-9f54-917178929af9' User entered 'No (N)'	System	07 Mar 2021 05:30:10
	System	07 Mar 2021 05:30:10

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-03-07T00:30:03-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3c8186e8-43b4-4569-9f54-917178929af9'	System	07 Mar 2021 05:30:10
User entered 'No (N)'	System	07 Mar 2021 05:30:10

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-03-07T00:30:06-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3c8186e8-43b4-4569-9f54-917178929af9' User entered '07 Mar 2021 00:30:06'	System	07 Mar 2021 05:30:10
	System	07 Mar 2021 05:30:10

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-03-17T12:19:14-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1d7eb817-1f98-4246-84b6-b975ff558ef4'	System	17 Mar 2021 16:19:28
User entered 'No (N)'	System	17 Mar 2021 16:19:28

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-03-17T12:19:17-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1d7eb817-1f98-4246-84b6-b975ff558ef4'	System	17 Mar 2021 16:19:28
User entered 'No (N)'	System	17 Mar 2021 16:19:28

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-03-17T12:19:19-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '1d7eb817-1f98-4246-84b6-b975ff558ef4'	System	17 Mar 2021 16:19:28
User entered '17 Mar 2021 12:19:19'	System	17 Mar 2021 16:19:28

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-03-22T19:26:55-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b3b873e4-6bd6-4cf8-8a78-2a3474f81fec'	System	22 Mar 2021 23:27:06
User entered 'No (N)'	System	22 Mar 2021 23:27:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-03-22T19:26:59-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b3b873e4-6bd6-4cf8-8a78-2a3474f81fec'	System	22 Mar 2021 23:27:06
User entered 'No (N)'	System	22 Mar 2021 23:27:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-03-22T19:27:01-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'b3b873e4-6bd6-4cf8-8a78-2a3474f81fec'	System	22 Mar 2021 23:27:06
User entered '22 Mar 2021 19:27:01'	System	22 Mar 2021 23:27:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-03-30T09:34:08-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3cb38ff0-c084-4c47-9aca-c5fb69e3b118'	System	30 Mar 2021 13:34:18
User entered 'No (N)'	System	30 Mar 2021 13:34:18

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-03-30T09:34:10-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3cb38ff0-c084-4c47-9aca-c5fb69e3b118'	System	30 Mar 2021 13:34:18
User entered 'No (N)'	System	30 Mar 2021 13:34:18

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-03-30T09:34:12-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '3cb38ff0-c084-4c47-9aca-c5fb69e3b118'	System	30 Mar 2021 13:34:18
User entered '30 Mar 2021 09:34:12'	System	30 Mar 2021 13:34:18

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-04-06T23:35:29-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '18ce3665-5512-427c-b995-bb5b41a875ce'	System	07 Apr 2021 03:35:37
User entered 'No (N)'	System	07 Apr 2021 03:35:37

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-04-06T23:35:31-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '18ce3665-5512-427c-b995-bb5b41a875ce'	System	07 Apr 2021 03:35:37
User entered 'No (N)'	System	07 Apr 2021 03:35:37

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-04-06T23:35:33-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '18ce3665-5512-427c-b995-bb5b41a875ce' User entered '06 Apr 2021 23:35:33'	System	07 Apr 2021 03:35:37
	System	07 Apr 2021 03:35:37

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-04-13T18:00:00-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'f862ede5-c48c-40b8-939f-c054c8920cdb' User entered 'No (N)'	System	13 Apr 2021 22:00:12

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-04-13T18:00:03-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'f862ede5-c48c-40b8-939f-c054c8920cdb' User entered 'No (N)'	System	13 Apr 2021 22:00:12

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-04-13T18:00:06-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'f862ede5-c48c-40b8-939f-c054c8920cdb' User entered '13 Apr 2021 18:00:06'	System	13 Apr 2021 22:00:12

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-04-18T23:07:43-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bcc418c3-7afa-4d50-9443-416ea0b1c756'	System	19 Apr 2021 03:07:53
User entered 'No (N)'	System	19 Apr 2021 03:07:53

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-04-18T23:07:48-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bcc418c3-7afa-4d50-9443-416ea0b1c756'	System	19 Apr 2021 03:07:53
User entered 'No (N)'	System	19 Apr 2021 03:07:53

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-04-18T23:07:50-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'bcc418c3-7afa-4d50-9443-416ea0b1c756'	System	19 Apr 2021 03:07:53
User entered '18 Apr 2021 23:07:50'	System	19 Apr 2021 03:07:53

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-04-24T11:08:08-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '44b07e52-5155-4d0d-bcce-97e8d7a735cf' User entered 'No (N)'	System	24 Apr 2021 15:08:15
	System	24 Apr 2021 15:08:15

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-04-24T11:08:10-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '44b07e52-5155-4d0d-bcce-97e8d7a735cf' User entered 'No (N)'	System	24 Apr 2021 15:08:15

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-04-24T11:08:12-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: '44b07e52-5155-4d0d-bcce-97e8d7a735cf' User entered '24 Apr 2021 11:08:12'	System	24 Apr 2021 15:08:15
	System	24 Apr 2021 15:08:15

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[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 (7ac9e593973cbf1f)', Time: '2021-05-01T00:01:38-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c467d55a-1e7e-4821-ac7d-ff02588ddbfb'	System	01 May 2021 04:54:28
User entered 'No (N)'	System	01 May 2021 04:54:28

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Have you been exposed to someone with 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 (7ac9e593973cbf1f)', Time: '2021-05-01T00:01:42-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c467d55a-1e7e-4821-ac7d-ff02588ddbfb'	System	01 May 2021 04:54:28
User entered 'No (N)'	System	01 May 2021 04:54:28

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-05-01T00:01:45-04:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'c467d55a-1e7e-4821-ac7d-ff02588ddbfb'	System	01 May 2021 04:54:28
User entered '01 May 2021 00:01:45'	System	01 May 2021 04:54:28

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '10 Dec 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '14 Dec 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '17 Dec 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '21 Dec 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '24 Dec 2022 00:01'	System	20 Nov 2020 13:32:06

US3632154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:55:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:06
Amendment Manager: User entered '28 Dec 2022 23:59'	System	20 Nov 2020 13:32:06

US3632154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:55:49

[Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:46:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-02-28T21:44:09-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cca594d4-36b4-4966-a180-5bf0b41f8ef6'	System	01 Mar 2021 02:47:19
User entered 'Yes (Y)'	System	01 Mar 2021 02:47:19

US3632154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:55:49

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:46:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-02-28T21:44:16-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cca594d4-36b4-4966-a180-5bf0b41f8ef6'	System	01 Mar 2021 02:47:19
User entered 'Yes (Y)'	System	01 Mar 2021 02:47:19

US3632154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:55:49

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:46:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7ac9e593973cbf1f)', Time: '2021-02-28T21:44:18-05:00', User OID: 'PatientReportedOutcome (US3632154)', ODM File OID: 'cca594d4-36b4-4966-a180-5bf0b41f8ef6'	System	01 Mar 2021 02:47:19
User entered '28 Feb 2021 21:44:18'	System	01 Mar 2021 02:47:19

US3632154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4)	14 Jan 2021 21:24:20
	(b) (4), (b) (6)	

US3632154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '14 Jan 2021'	(b) (4)	14 Jan 2021 21:24:20
	(b) (4), (b) (6)	

US3632154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 21:24:20

US3632154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4)	14 Jan 2021 21:24:20
	(b) (4), (b) (6)	

US3632154

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4)	14 Jan 2021 21:24:29
	(b) (4), (b) (6)	

US3632154

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 04:49:23
User entered 'I'	System	14 Jan 2021 21:24:29

US3632154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 19:53:03

US3632154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '17 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 19:53:03

US3632154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Feb 2021 19:53:03

US3632154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:53:03

US3632154

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 19:53:43

US3632154

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User entered '1'	System	17 Feb 2021 19:53:43

US3632154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 16:30:56

US3632154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 16:30:56

US3632154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Mar 2021 16:30:56

US3632154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 16:30:56

US3632154

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 16:31:02

US3632154

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:05:39
User entered '1'	System	19 Mar 2021 16:31:02

US3632154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:53:05

US3632154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:53:05

US3632154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:53:05

US3632154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:53:05

US3632154

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:53:08

US3632154

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 12:53:08

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:49

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:07
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	27 Jan 2021 17:11:21
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 10-DEC-2020 is reported under Illness Visit Day1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 12:16:34
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 10-DEC-2020 is reported under Illness Visit Day1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 15:14:05
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 10-DEC-2020 is reported under Illness Visit Day1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:13:44
User entered '9 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 21:46:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:49

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:02
User closed query 'Time on progress note in the source is noted as 12:35; please confirm and update RDC.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 06:29:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
Query 'Time on progress note in the source is noted as 12:35; please confirm and update RDC.' answered with 'Updated time' (Site from CRA).	Isaac Perez (b) (4)	15 Feb 2021 20:20:49
User entered '12:35' reason for change: Data Entry Error	Isaac Perez (b) (4)	15 Feb 2021 20:20:44
User opened query 'Time on progress note in the source is noted as 12:35; please confirm and update RDC.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 17:23:58
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 17:11:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:11:21
User entered '14:00'	(b) (4), (b) (6)	10 Dec 2020 21:46:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:49

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:07
User entered '9 Dec 2020 12:35'	System	15 Feb 2021 20:20:44
User entered '9 Dec 2020 14:00'	System	10 Dec 2020 21:46:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:49

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:07
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:11:21
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	10 Dec 2020 21:46:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:55:49

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:07
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:11:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 21:46:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 21:27:34
User entered '8 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 21:27:34
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:34
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 21:27:34
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:48:30

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered '9 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'Severe (Severe)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'Severe (Severe)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 21:27:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'Severe (Severe)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'Severe (Severe)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:27:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:50:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:52:06

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 21:28:50
User entered '10 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered '97'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered '98.9' F	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Jan 2021 21:48:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Severe (Severe)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Severe (Severe)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Severe (Severe)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:28:50
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 21:28:50
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 21:52:06

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 4 (Day 4)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered '11 Dec 2020'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered '0'	Christina Bacher (b) (4) (b) (4)	11 Dec 2020 20:24:56

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered '97'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	11 Dec 2020 20:24:56

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered '97.9' F	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	11 Dec 2020 20:24:56

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	11 Dec 2020 20:24:56

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	11 Dec 2020 20:24:56

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	23 Jan 2021 21:46:29
Data Entry Error		
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Severe (Severe)' reason for change:	(b) (4), (b) (6)	23 Jan 2021 21:46:29
Data Entry Error		
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	11 Dec 2020 20:24:56

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:58:08
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:24:56

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	12 Dec 2020 22:15:24

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered '12 Dec 2020'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered '0'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered '97'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered '97.4' F	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'Severe (Severe)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:15
User entered 'None (None)'	(b) (4), (b) (6)	12 Dec 2020 22:15:24

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered '13 Dec 2020'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered '0'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered '96'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered '98.7' F	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Severe (Severe)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'Severe (Severe)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:19
User entered 'None (None)'	(b) (4), (b) (6)	13 Dec 2020 21:33:19

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 22:05:27
User entered '14 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 22:05:27
User entered '94'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered '100.3' F	(b) (4), (b) (6)	14 Dec 2020 20:33:01

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 22:05:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 22:05:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 22:05:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'Severe (Severe)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 22:05:27
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:27
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 22:05:27
User entered 'None (None)'	(b) (4), (b) (6)	14 Dec 2020 20:33:01

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 8 (Day 8)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered '15 Dec 2020'	Christina Bacher (b) (4) (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered '0'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered '92'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered '98.6' F	Christina Bacher (b) (4)	15 Dec 2020 20:59:19
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Mild (Mild)'	Christina Bacher (b) (4) (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'Severe (Severe)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'None (None)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'None (None)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'None (None)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'None (None)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'None (None)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:31
User entered 'None (None)'	Christina Bacher (b) (4)	15 Dec 2020 20:59:19

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 9 (Day 9)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered '16 Dec 2020'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered '0'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered '98'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	16 Dec 2020 20:17:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered '97.6' F	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Christina Bacher (b) (4)	17 Dec 2020 20:53:05
User entered 'None (None)'	(b) (4)	
	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'Mild (Mild)'	Christina Bacher (b) (4) (b) (4)	16 Dec 2020 20:17:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'Mild (Mild)'	Christina Bacher (b) (4) (b) (4)	16 Dec 2020 20:17:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'None (None)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	16 Dec 2020 20:17:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'Severe (Severe)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'None (None)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'None (None)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'None (None)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'None (None)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'None (None)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:34
User entered 'None (None)'	Christina Bacher (b) (4)	16 Dec 2020 20:17:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 10 (Day 10)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered '17 Dec 2020'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered '0'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered '98'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered '97.4' F	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'Severe (Severe)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:05:39
User entered 'None (None)'	Christina Bacher (b) (4)	17 Dec 2020 20:53:05

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 11 (Day 11)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered '18 Dec 2020'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered '0'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered '94'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	21 Dec 2020 14:42:50

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered '97.6' F	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4) (b) (4)	21 Dec 2020 14:42:50

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	21 Dec 2020 14:42:50

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'Severe (Severe)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:08
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:42:50
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 12 (Day 12)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered '19 Dec 2020'	Christina Bacher (b) (4) (b) (4)	21 Dec 2020 14:48:12

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered '0'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered '96'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	21 Dec 2020 14:48:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered '98.1' F	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Form: Symptom Log (12)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'Severe (Severe)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:11
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:48:12
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 13 (Day 13)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered '20 Dec 2020'	Christina Bacher (b) (4) (b) (4)	21 Dec 2020 14:49:32

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered '0'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered '97'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	21 Dec 2020 14:49:32

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered '98.9' F	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'Severe (Severe)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:15
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 14:49:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 14 (Day 14)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered '21 Dec 2020'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered '0'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered '95'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	21 Dec 2020 21:33:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered '98.6' F	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	21 Dec 2020 21:33:32

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:17
User entered 'None (None)'	Christina Bacher (b) (4)	21 Dec 2020 21:33:32
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 15 (Day 15)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered '22 Dec 2020'	Christina Bacher (b) (4) (b) (4)	23 Dec 2020 14:01:58

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered '0'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered '98'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	23 Dec 2020 14:01:58

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered '97.4' F	Christina Bacher (b) (4)	23 Dec 2020 14:01:58
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4) (b) (4)	23 Dec 2020 14:01:58

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4) (b) (4)	23 Dec 2020 14:01:58

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'Mild (Mild)'	Christina Bacher (b) (4) (b) (4)	23 Dec 2020 14:01:58

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	23 Dec 2020 14:01:58

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4) (b) (4)	23 Dec 2020 14:01:58

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:26
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 14:01:58

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 16 (Day 16)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered '23 Dec 2020'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered '0'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered '98'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered '97.5' F	Christina Bacher (b) (4) (b) (4)	23 Dec 2020 20:36:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17
	(b) (4)	

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17
	(b) (4)	

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4) (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'Severe (Severe)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:33
User entered 'None (None)'	Christina Bacher (b) (4)	23 Dec 2020 20:36:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	27 Dec 2020 01:05:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered '24 Dec 2020'	(b) (4), (b) (6)	27 Dec 2020 01:05:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered 'l'	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered empty.	System	27 Dec 2020 01:05:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:35
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:17

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 18 (Day 18)'	(b) (4) (b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered '25 Dec 2020'	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered 'l'	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered empty.	System	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:39
User entered empty.	(b) (4), (b) (6)	27 Dec 2020 01:05:51

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Day 19 (Day 19)'	(b) (4) (b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered '26 Dec 2020'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered '0'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered '96'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User entered '%'	System	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered '98.4' F	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'Mild (Mild)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:55:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:12:43
User entered 'None (None)'	(b) (4), (b) (6)	27 Dec 2020 01:08:42

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Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:49

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:15:04
User entered '10 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 14:32:41

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Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:49

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:15:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 14:32:41

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Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:49

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:15:04
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 09:21:55
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed positive' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 14:32:51
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	15 Dec 2020 14:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 14:32:41

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Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:49

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:15:04
User entered '10 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 14:32:41

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Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:49

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:15:04
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	15 Dec 2020 14:32:41

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Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:49

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:15:04
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:32:41

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Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

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[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)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:15:04
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:32:41

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Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:49

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:15:04
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:32:41

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Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:49

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:15:04
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:32:41

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Folder: Covid-19 Assessment 09 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:55:49

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:23
Data entry locked.	(b) (4), (b) (6)	04 May 2021 00:22:20
User entered 'I'	System	15 Dec 2020 14:32:41

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty; reason for change New Information	Christina Bacher (b) (4)	21 Jan 2021 21:41:23
User entered '15 Dec 2020' reason for change: New Information	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:36:38
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty; reason for change New Information	Christina Bacher (b) (4)	21 Jan 2021 21:41:23
User entered '15 Dec 2020' reason for change: New Information	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:36:38
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User closed query 'Per CDM; Per symptom log Day 8, O2 Saturations is recorded as 92%; however, 'Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?' is recorded as No. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:08:10
Query 'Per CDM; Per symptom log Day 8, O2 Saturations is recorded as 92%; however, 'Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?' is recorded as No. Please review and update accordingly' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:22:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:22:46
User opened query 'Per CDM; Per symptom log Day 8, O2 Saturations is recorded as 92%; however, 'Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?' is recorded as No. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 17:52:58
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered '15 Dec 2020' reason for change: New Information	Christina Bacher (b) (4)	21 Jan 2021 21:41:23
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered '15 Dec 2020' reason for change: New Information	Christina Bacher (b) (4)	21 Jan 2021 21:41:23
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 05:41:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User closed query 'Per CDM : Kindly update the oxygen saturation %.Thanks ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 11:42:27
Query 'Per CDM : Kindly update the oxygen saturation %.Thanks ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 17:50:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:49:46
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 17:49:46
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 17:49:46
User opened query 'Per CDM : Kindly update the oxygen saturation %.Thanks ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 10:24:51
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 14:33:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:33:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 14:33:59
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 14:33:46
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

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Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Generated On: 11 Aug 2021 22:55:49

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 14:34:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 14:34:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 14:34:03
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 14:33:46
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 05:41:57
User closed query 'Per CDM: Please note that this field should remain empty when the two questions above are answered with "No". Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 04:48:43
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
Query 'Per CDM: Please note that this field should remain empty when the two questions above are answered with "No". Kindly update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 14:20:59
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 14:20:42
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 14:20:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 14:20:42
User opened query 'Per CDM: Please note that this field should remain empty when the two questions above are answered with "No". Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 11:46:15
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Generated On: 11 Aug 2021 22:55:49

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Generated On: 11 Aug 2021 22:55:49

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

US3632154

Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per CDM re-query. Response noted. However, as per CCG V4.0 page 47, the fields (Evidence of shock Requires Vasopressors, acute renal dysfunction, hepatic dysfunction, neurologic dysfunction, Radiographical evidence) requires YES/NO response. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 03:55:09
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:49
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
Query 'Per CDM re-query. Response noted. However, as per CCG V4.0 page 47, the fields (Evidence of shock Requires Vasopressors, acute renal dysfunction, hepatic dysfunction, neurologic dysfunction, Radiographical evidence) requires YES/NO response. Please reconcile and update accordingly.' answered with 'updated' (Site from DM).	Christina Bacher (b) (4)	21 Jan 2021 21:40:07
User opened query 'Per CDM re-query. Response noted. However, as per CCG V4.0 page 47, the fields (Evidence of shock Requires Vasopressors, acute renal dysfunction, hepatic dysfunction, neurologic dysfunction, Radiographical evidence) requires YES/NO response. Please reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 05:08:11
User closed query 'Per CDM:Requery:Response noted,however no data has been updated.Kindly review and update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 05:08:11
Query 'Per CDM:Requery:Response noted,however no data has been updated.Kindly review and update accordingly.Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 20:10:56

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
User opened query 'Per CDM:Requery:Response noted,however no data has been updated.Kindly review and update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:09:51
User closed query 'Per CDM: Please review Evidence of Shock section and update accordingly as it appears some responses are missing.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:08:52
Query 'Per CDM: Please review Evidence of Shock section and update accordingly as it appears some responses are missing.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:23:08
User opened query 'Per CDM: Please review Evidence of Shock section and update accordingly as it appears some responses are missing.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 17:48:17
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Form: Covid-19 Severity Assessment

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[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)' reason for change: Data Entry Error	Christina Bacher (b) (4)	21 Jan 2021 21:39:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)' reason for change: Data Entry Error	Christina Bacher (b) (4)	21 Jan 2021 21:39:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)' reason for change: Data Entry Error	Christina Bacher (b) (4)	21 Jan 2021 21:39:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)' reason for change: Data Entry Error	Christina Bacher (b) (4)	21 Jan 2021 21:39:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:01:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per CDM: Please record YES/ NO response to "Radiographical Evidence" field and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 12:01:20
Query 'Per CDM: Please record YES/ NO response to "Radiographical Evidence" field and update accordingly. ' answered with 'Selection updated' (Site from DM).	Isaac Perez (b) (4)	15 Feb 2021 20:21:19
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	15 Feb 2021 20:21:12
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 17:26:54
User opened query 'Per CDM: Please record YES/ NO response to "Radiographical Evidence" field and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 03:55:31
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:01:06
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 17:26:57
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:55:49

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:17:16
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 14:33:46

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Folder: Covid-19 Assessment 09 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:55:49

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:22:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:01:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Sarah Wiatrek (b) (4) (b) (4)	08 Feb 2021 19:52:30

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:55:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Dec 2020 22:27:30

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:55:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:21:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Dec 2020 22:27:30

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:55:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:21:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 05:14:22
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Day 3 saliva resulted in PPD 18DEC2020. Accession number for day 3 and day 5 saliva 1F60NEF. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 15:56:56
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 06:14:39
User entered '12 Dec 2020'	(b) (4), (b) (6)	12 Dec 2020 22:27:30

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:55:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	12 Dec 2020 22:27:30

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:55:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	08 Jan 2021 21:22:05
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:31:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 20:31:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 20:31:32
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Dec 2020 22:27:30
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:55:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 21:22:05
User entered '14 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Dec 2020 20:31:32
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:55:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:55:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	27 Jan 2021 17:30:39
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 21:52:25
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:34:49
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 19:10:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 19:10:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Christina Bacher (b) (4)	16 Dec 2020 19:10:26
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Dec 2020 22:27:30
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:55:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:30:39
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 21:52:25
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:34:49
User entered '16 Dec 2020' reason for change: Data Entry Error	Christina Bacher (b) (4)	16 Dec 2020 19:10:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:55:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:55:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:52:32
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Dec 2020 17:55:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 10:46:35
Query 'Data is required. Please complete.' answered with 'Date has not occurred yet' (Site from System).	Bezuayehu Mandefro (b) (4)	17 Dec 2020 17:13:34
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Dec 2020 22:27:30
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:55:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:52:32
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Visit 2 Day 29 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)	22 Jan 2021 04:26:48
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Visit 2 Day 29 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 'Day 9 saliva collected and resulted from PPD on 23DEC2020' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:25:07
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Visit 2 Day 29 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)	29 Dec 2020 08:41:59
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:55:21
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:55:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:55:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	27 Jan 2021 17:30:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:25:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 10:46:46
Query 'Data is required. Please complete.' answered with 'Date has not occurred yet' (Site from System).	Bezuayehu Mandefro (b) (4)	17 Dec 2020 17:13:43
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Dec 2020 22:27:30
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:55:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:30:57
User entered '23 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:25:37
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:55:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:55:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	27 Jan 2021 17:31:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:26:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 10:46:51
Query 'Data is required. Please complete.' answered with 'Date has not occurred yet' (Site from System).	Bezuayehu Mandefro (b) (4)	17 Dec 2020 17:13:53
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Dec 2020 22:27:30
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:55:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:31:11
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:55:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:55:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	27 Jan 2021 17:32:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:24:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 10:46:56
Query 'Data is required. Please complete.' answered with 'Date has not occurred yet' (Site from System).	Bezuayehu Mandefro (b) (4)	17 Dec 2020 17:14:29
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Dec 2020 22:27:30
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:55:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:32:12
User entered '6 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 19:56:12
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 22:27:30

US3632154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:10
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:17:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 21:44:28

US3632154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:10
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:17:52
User entered '10 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 21:44:28

US3632154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[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 20:15:10
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:17:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Dec 2020 21:44:28

US3632154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:10
User entered 'SICKD1'	System	10 Dec 2020 21:44:28

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 21:18:15
	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered '10 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered '15:22'	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User entered '10 Dec 2020 15:22'	System	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered '63.5' in	(b) (4), (b) (6)	10 Dec 2020 21:45:53
DataPoint set to visible.	System	10 Dec 2020 21:44:28

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered '226.4' lb	(b) (4), (b) (6)	10 Dec 2020 21:45:53
DataPoint set to visible.	System	10 Dec 2020 21:44:28

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered '98.9' F	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered '100'	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User entered 'bpm'	System	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered '18'	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User entered 'breaths/min'	System	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered '139'	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User entered 'mmHg'	System	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:15
User entered '84'	(b) (4), (b) (6)	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14
User entered 'mmHg'	System	10 Dec 2020 21:45:53

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14

US3632154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:14

US3632154

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:18
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 21:46:01

US3632154

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:18
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:37
User entered '10 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 21:46:01

US3632154

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:55:49

[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 20:15:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 21:46:24

US3632154

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:55:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:15:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 21:18:50
User entered '10 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 21:46:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 19:56:30

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:43
User entered '6 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 19:56:30

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Jan 2021 19:56:30

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:31
User entered 'SICKD28'	System	06 Jan 2021 19:56:30

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered '6 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered '12:05'	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User entered '6 Jan 2021 12:05'	System	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Jan 2021 19:57:24
DataPoint set to visible.	System	06 Jan 2021 19:56:30

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Jan 2021 19:57:24
DataPoint set to visible.	System	06 Jan 2021 19:56:30

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered '97.7' F	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered '91'	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User entered 'bpm'	System	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered '14'	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User entered 'breaths/min'	System	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered '117'	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User entered 'mmHg'	System	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:19:55
User entered '69'	(b) (4), (b) (6)	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41
User entered 'mmHg'	System	06 Jan 2021 19:57:24

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:41

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:48
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:21:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 19:57:31

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:48
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:21:09
User entered '6 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 19:57:31

US3632154

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:55:49

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:21:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 19:57:37

US3632154

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:55:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 22:21:18
User entered '6 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 19:57:37

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	06 Jan 2021 19:56:30

US3632154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	06 Jan 2021 19:56:30

US3632154

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:00:38

US3632154

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:00:38

US3632154

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Jan 2021 19:00:38

US3632154

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

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 19:00:38

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:02:27

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[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 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered '0'	Aastha KC (b) (4)	09 Apr 2021 12:31:13
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:58:17

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:02:27

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User closed query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 16:27:15
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
Query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'the participant was unblinded under amendment six. ' (Site from DM).	Aastha KC (b) (4)	09 Apr 2021 12:31:22
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	09 Apr 2021 12:31:13
User opened query 'Per CDA, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:29:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:58:17

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:02:27

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:02:27

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:02:27

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:02:27

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:02:27

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '1'	System	22 Jan 2021 19:02:27

US3632154

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

Form: Unblinding

Generated On: 11 Aug 2021 22:55:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'I'	System	22 Jan 2021 19:02:27

US3632154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '62.5' in	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '225' lb	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '40.58190'	System	22 Jan 2021 19:05:22
DataPoint set to visible.	System	22 Jan 2021 19:02:27

US3632154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '62.5' in	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '225' lb	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '40.58190'	System	22 Jan 2021 19:05:22
DataPoint set to visible.	System	22 Jan 2021 19:02:27

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '09:50'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '22 Jan 2021 09:50'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '97.5' F	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '87'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'bpm'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '20'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'breaths/min'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '120'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'mmHg'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '81'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'mmHg'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '62.5' in	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '225' lb	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '40.58190'	System	22 Jan 2021 19:05:22
DataPoint set to visible.	System	22 Jan 2021 19:02:27

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '11:25'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '22 Jan 2021 11:25'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '97.8' F	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '85'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'bpm'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '18'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'breaths/min'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '126'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'mmHg'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '81'	(b) (4), (b) (6)	22 Jan 2021 19:05:22

US3632154

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'mmHg'	System	22 Jan 2021 19:05:22

US3632154

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:05:31

US3632154

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:05:31

US3632154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:06:12

US3632154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:06:12

US3632154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Jan 2021 19:06:12

US3632154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:06:12

US3632154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but FSH collection date and time has been recorded. If FSH indicated as "No" Date and Time should be blank. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 06:13:36
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but FSH collection date and time has been recorded. If FSH indicated as "No" Date and Time should be blank. Please review and update accordingly. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 22:24:38
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but FSH collection date and time has been recorded. If FSH indicated as "No" Date and Time should be blank. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 07:41:02
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 19:06:12

US3632154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:24:26
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:06:12

US3632154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:24:26
User entered '10:30'	(b) (4), (b) (6)	22 Jan 2021 19:06:12

US3632154

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered empty.	System	01 Feb 2021 22:24:26
User entered '22 Jan 2021 10:30'	System	22 Jan 2021 19:06:12

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:06:43

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:06:43

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 19:06:43

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'mRNA-1273'	System	22 Jan 2021 19:06:43
DataPoint set to visible.	System	22 Jan 2021 19:02:27

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:06:43

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '10:50'	(b) (4), (b) (6)	22 Jan 2021 19:06:43

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '22 Jan 2021 10:50'	System	22 Jan 2021 19:06:43

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:06:43

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'ONCE'	System	22 Jan 2021 19:06:43

US3632154

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

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 19:06:43

US3632154

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 19:07:13

US3632154

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:07:13

US3632154

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '10:32'	(b) (4), (b) (6)	22 Jan 2021 19:07:13

US3632154

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '22 Jan 2021 10:32'	System	22 Jan 2021 19:07:13

US3632154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:07:36

US3632154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:49

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '22 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 19:07:36

US3632154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '10:34'	(b) (4), (b) (6)	22 Jan 2021 19:07:36

US3632154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered '22 Jan 2021 10:34'	System	22 Jan 2021 19:07:36

US3632154

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

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:07:45

US3632154

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

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:21
User entered 'I'	System	22 Jan 2021 19:07:45

US3632154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:18
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 21:50:04

US3632154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:18
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered '29 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 21:50:04

US3632154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:18
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Jan 2021 21:50:04

US3632154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:18
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 21:50:04

US3632154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:18
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 21:50:07

US3632154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:18
User entered 'I'	System	29 Jan 2021 21:50:07

US3632154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:18
User entered 'I'	System	29 Jan 2021 21:50:07
DataPoint set to visible.	System	29 Jan 2021 21:50:07

US3632154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	Isaac Perez (b) (4)	18 Feb 2021 20:07:10

US3632154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '18 Feb 2021'	Isaac Perez (b) (4)	18 Feb 2021 20:07:10

US3632154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[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 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Clinic (Clinic)'	Isaac Perez (b) (4)	18 Feb 2021 20:07:10

US3632154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'OLD29'	System	18 Feb 2021 20:07:10

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User accepted default value 'Pre-Dose (PREDOSE)'	Isaac Perez (b) (4) (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '18 Feb 2021'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '14:19'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered '18 Feb 2021 14:19'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '97.8' F	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (Oral)'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '80'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'bpm'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '14'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'breaths/min'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '123'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'mmHg'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '80'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'mmHg'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User accepted default value 'Post-Dose (POSTDOSE)'	Isaac Perez (b) (4) (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '18 Feb 2021'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '15:47'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered '18 Feb 2021 15:47'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '98.0' F	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (Oral)'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '78'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'bpm'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '12'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'breaths/min'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '131'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'mmHg'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '84'	Isaac Perez (b) (4)	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'mmHg'	System	18 Feb 2021 21:05:05

US3632154

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	Isaac Perez (b) (4)	18 Feb 2021 20:07:18

US3632154

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '18 Feb 2021'	Isaac Perez (b) (4)	18 Feb 2021 20:07:18

US3632154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	Isaac Perez (b) (4)	18 Feb 2021 20:30:13

US3632154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '18 Feb 2021'	Isaac Perez (b) (4)	18 Feb 2021 20:30:13

US3632154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Urine (URINE)'	Isaac Perez (b) (4)	18 Feb 2021 20:30:13

US3632154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Negative (NEGATIVE)'	Isaac Perez (b) (4)	18 Feb 2021 20:30:13

US3632154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	Isaac Perez (b) (4)	18 Feb 2021 20:30:13

US3632154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Isaac Perez (b) (4)	18 Feb 2021 20:30:13

US3632154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Isaac Perez (b) (4)	18 Feb 2021 20:30:13

US3632154

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:55:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered empty.	System	18 Feb 2021 20:30:13

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	Isaac Perez (b) (4)	18 Feb 2021 20:30:33

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Isaac Perez (b) (4)	18 Feb 2021 20:30:33

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Isaac Perez (b) (4)	18 Feb 2021 20:30:33

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'mRNA-1273'	System	18 Feb 2021 20:30:33
DataPoint set to visible.	System	29 Jan 2021 21:50:07

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '18 Feb 2021'	Isaac Perez (b) (4)	18 Feb 2021 20:30:33

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '15:15'	Isaac Perez (b) (4)	18 Feb 2021 20:30:33

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered '18 Feb 2021 15:15'	System	18 Feb 2021 20:30:33

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Left Arm (LEFT ARM)'	Isaac Perez (b) (4)	18 Feb 2021 20:30:33

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'ONCE'	System	18 Feb 2021 20:30:33

US3632154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:55:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'INTRAMUSCULAR'	System	18 Feb 2021 20:30:33

US3632154

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	Isaac Perez (b) (4)	18 Feb 2021 20:30:40

US3632154

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:50
User entered 'I'	System	18 Feb 2021 20:30:40

US3632154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'Yes (Y)'	Christina Bacher (b) (4)	25 Feb 2021 19:05:06

US3632154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered '25 Feb 2021'	Christina Bacher (b) (4)	25 Feb 2021 19:05:06

US3632154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	25 Feb 2021 19:05:06

US3632154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:55:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	Christina Bacher (b) (4)	25 Feb 2021 19:05:06

US3632154

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:01
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'Yes (Y)'	Christina Bacher (b) (4)	25 Feb 2021 19:05:08

US3632154

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:55:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:02:01
User entered 'I'	System	25 Feb 2021 19:05:08

US3632154

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 19:14:25

US3632154

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:14:25

US3632154

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[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 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:14:25

US3632154

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:55:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User entered 'OLD57'	System	18 Mar 2021 19:14:25

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User entered empty.	System	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User entered empty.	System	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User entered empty.	System	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User entered empty.	System	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User entered empty.	System	18 Mar 2021 19:14:35

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17

US3632154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:55:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17

US3632154

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 19:14:40

US3632154

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:55:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 19:14:40

US3632154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 19:15:44

US3632154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered '18 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 19:15:44

US3632154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User entered '14:39'	(b) (4), (b) (6)	18 Mar 2021 19:15:44

US3632154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:55:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:17
User entered '18 Mar 2021 14:39'	System	18 Mar 2021 19:15:44

US3632154

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:55:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:30
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:33:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:05:03

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Bilateral pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 18:21:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 18:21:38
Data point term sent to Coder	System	12 Nov 2020 18:08:08
User entered 'Two Small Bilateral Pleural Effusions'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '5 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:07:45

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User entered empty.	System	12 Nov 2020 18:07:45

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)' reason for change: New Information	Christina Bacher (b) (4)	10 Dec 2020 21:58:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '27 Nov 2020' reason for change: New Information	Christina Bacher (b) (4)	10 Dec 2020 21:58:30
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User entered empty.	System	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

US3632154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'None (NONE)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Other Action Taken field ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 06:16:25
Query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Other Action Taken field ' answered with 'Procedure has been included under con procedure- THORACENTESIS' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:47:43
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Other Action Taken field ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 04:16:19
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 04:40:40
Query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update. Else clarify. ' answered with 'THIS IS A CONCOMITANT PROCEDURE.' (Site from DM).	Kelly Likos (b) (4)	30 Nov 2020 15:28:30
User opened query 'Per CDM: Concomitant medication checked however concomitant medication page is missing. Kindly review and update. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 19:24:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Christina Bacher (b) (4)	10 Dec 2020 21:58:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Participant reported she had a cervical spine and thoracic spine x-ray on 29Oct2020 for her back spasms and neck pain. The c-rays demonstrated a growth on the pituitary gland. The doctor then ordered a chest x-ray on 05Nov2020 which demonstrated two small bilateral pleural effusions.'	(b) (4), (b) (6)	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User entered '0'	System	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52
User entered 'I'	System	12 Nov 2020 18:07:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:55:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 21:34:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:41
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:24:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 11:24:42
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	05 Apr 2021 01:19:29
Data point term sent to Coder	System	31 Mar 2021 15:02:26
User closed query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from System).	System	31 Mar 2021 15:02:02
Query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' answered with 'Per participant's report, chest tightness was due to COVID-19. Please see narrative' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 15:02:02
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 15:01:49
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 15:01:49
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 15:01:49
User entered 'CHEST TIGHTNESS (COVID-19 Related)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:01:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from System). User signature succeeded.	Coder Import (b) (4) (b) (4)	31 Mar 2021 14:53:01
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Tightness is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Tightness is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'Please see audit trail. The participant tested positive for COVID 19. The tightness was non-cardiac.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Feb 2021 18:46:08
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Tightness is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:36:26
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 01:38:35
		04 Feb 2021 06:00:28

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Yes it was. Participant was diagnosed with COVID-19. Please see narrative' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 13:39:37
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	(b) (4), (b) (6)	02 Feb 2021 17:12:18
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 22:05:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	10 Dec 2020 22:05:51
Data point term sent to Coder	System	10 Dec 2020 22:04:22
User entered 'Chest tightness'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '9 Dec 2020'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User entered empty.	System	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:20:50
User entered 'Yes (Y)'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:20:50
User entered empty.	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User entered empty.	System	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

US3632154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

US3632154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Not Related (NOT RELATED)'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Not Related (NOT RELATED)'	Christina Bacher (b) (4) (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 03:59:24
Query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:21:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:20:50
User opened query 'Per CDM: Per CCG pg.43, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 16:54:03
User entered 'None (NONE)'	Christina Bacher (b) (4) (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Jan 2021 17:21:10
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:21:10
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Jan 2021 17:20:50
User entered '0'	Christina Bacher (b) (4) (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please confirm and consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 04:00:10
Query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please confirm and consider to complete the ConMed forms. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:21:07
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:20:50
User opened query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please confirm and consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 16:55:27
User entered '1'	Christina Bacher (b) (4) (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 19:40:40
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:34
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 17:20:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Christina Bacher (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	Christina Bacher (b) (4)	10 Dec 2020 22:04:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Participant had chest tightness and was seen in the ED. She was diagnosed with COVID-19 and discharged.'	Christina Bacher (b) (4) (b) (4)	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User entered '0'	System	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21
User entered '1'	System	10 Dec 2020 22:04:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:55:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:08:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered		
'USA-US120-2020-mRNA-1273-P301000011'	System	16 Dec 2020 15:35:49
User entered 'New'	(b) (4), (b) (6)	16 Dec 2020 15:35:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:38:57
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 20:58:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 20:58:01
Data point term sent to Coder	System	15 Dec 2020 20:56:45
User entered 'Symptomatic Covid-19'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '8 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	15 Dec 2020 20:56:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 20:56:29
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	15 Dec 2020 20:56:03
User entered '00:00'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 20:56:29
User entered '8 Dec 2020 00:00'	System	15 Dec 2020 20:56:03

US3632154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	07 Jan 2021 17:19:36
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Jan 2021 17:19:36
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	07 Jan 2021 17:19:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 17:39:23
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'PV Query: Event end date was reported as 22 Dec 2020, but symptoms were reported through 26 Dec 2020. End date should be when symptoms resolved. Please consider updating end date or, if not updating, explain.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 16:24:03
Query 'PV Query: Event end date was reported as 22 Dec 2020, but symptoms were reported through 26 Dec 2020. End date should be when symptoms resolved. Please consider updating end date or, if not updating, explain.' answered with 'other than taste and smell (which were reported through 26Dec), all symptoms had resolved by 12/22' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 15:03:51
User opened query 'PV Query: Event end date was reported as 22 Dec 2020, but symptoms were reported through 26 Dec 2020. End date should be when symptoms resolved. Please consider updating end date or, if not updating, explain.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:05:04
User closed query 'PV Query: Please provide the event end date (when symptoms resolved), when available' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 20:42:32
Query 'PV Query: Please provide the event end date (when symptoms resolved), when available' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:19:44
User entered '22 Dec 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Jan 2021 17:19:24
User opened query 'PV Query: Please provide the event end date (when symptoms resolved), when available' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:45:00
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

US3632154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

US3632154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:56:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 20:56:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 20:56:38
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:56:03
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:56:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 20:56:38
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 20:56:38
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:56:03
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	27 Jan 2021 17:38:57
	(b) (4), (b) (6)	
User closed query ' PV Query: As the last dose of study drug was given on 19 Nov 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 20:42:38
Query ' PV Query: As the last dose of study drug was given on 19 Nov 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:19:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Jan 2021 17:19:24
User opened query ' PV Query: As the last dose of study drug was given on 19 Nov 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:44:32
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:56:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 20:56:43
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 20:56:43
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:56:03
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

US3632154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered '0'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 20:42:42
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:20:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Jan 2021 17:19:24
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:45:20
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:56:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 20:56:29
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Dec 2020 20:56:29
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:56:03
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:38:57
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	27 Jan 2021 17:38:57
	(b) (4), (b) (6)	
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 20:43:05
User closed query 'PV Query: Please provide any additional COVID-19 testing from the emergency department visit if available.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 20:43:00
Query 'PV Query: Please confirm if the subject was hospitalized overnight' answered with 'No, was discharged from ED' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:19:21
Query 'PV Query: Please provide any additional COVID-19 testing from the emergency department visit if available.' answered with 'diagnosed in ED with covid-19 per narrative note' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:19:15
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:45:58
User opened query 'PV Query: Please provide any additional COVID-19 testing from the emergency department visit if available.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:45:44
User entered 'Participant was seen in ED 09DEC for shortness of breath and chest tightness, was diagnosed with covid-19 and discharged home. Seen following day by study staff for illness visit'	(b) (4), (b) (6)	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Dec 2020 20:56:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:55:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Dec 2020 20:56:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:55:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:30
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:48:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 15:21:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:21:38
Data point term sent to Coder	System	23 Oct 2020 14:51:20
User entered 'Lithium'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:51:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 14:51:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Schizoaffective Bipolar'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:51:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '450'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:51:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'mg (mg)'	Aastha KC (b) (4)	23 Oct 2020 14:51:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:51:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'three times daily (TID)'	Aastha KC (b) (4)	23 Oct 2020 14:51:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:51:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:51:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:51:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 Oct 2017'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:51:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:51:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:51:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:51:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:52:39
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:52:39
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:52:39
User entered empty.	(b) (4)	
	System	23 Oct 2020 14:51:03
	Aastha KC (b) (4)	23 Oct 2020 14:51:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Oct 2020 14:51:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 14:51:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 14:51:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 20:30:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 20:30:55
Data point term sent to Coder	System	10 Mar 2021 20:29:36
Coding entries removed.	(b) (4), (b) (6)	10 Mar 2021 20:28:39
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 20:28:39
User entered 'SEROQUEL' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 20:28:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:13:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:13:39
Data point term sent to Coder	System	23 Oct 2020 14:53:23
User entered 'Serguel'	Aastha KC (b) (4)	23 Oct 2020 14:52:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 14:53:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 14:53:01
User entered 'No (N)' reason for change: Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 14:53:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 14:52:53
User entered empty.	System	23 Oct 2020 14:52:53
	Aastha KC (b) (4)	23 Oct 2020 14:52:53
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Schizoaffective Bipolar'	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '100'	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 Oct 2017'	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
Signature has been broken.	(b) (4)	18 Mar 2021 19:17:27
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	18 Mar 2021 19:17:27
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
Signature has been broken.	(b) (4)	18 Mar 2021 19:17:27
User entered '06 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	18 Mar 2021 19:17:27
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4)	23 Oct 2020 14:52:53
	Aastha KC (b) (4)	
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 15:52:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:52:48
User entered 'No (N)' reason for change: Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 15:52:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 14:52:53
User entered empty.	System	23 Oct 2020 14:52:53
	Aastha KC (b) (4)	23 Oct 2020 14:52:53
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User entered '1'	System	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User entered '1'	System	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:14
User entered '804 (804)'	System	23 Oct 2020 14:52:53

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: ANTICHOLINERGIC AGENTS, ATC: ETHERS OF TROPINE OR TROPINE DERIVATIVES, PRODUCT: BENZATROPINE MESILATE, PRODUCTSYNONYM: COGENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:57:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:57:36
Data point term sent to Coder	System	23 Oct 2020 14:56:34
User entered 'Cogentin'	Aastha KC (b) (4)	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 14:56:03
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Schizoaffective Bipolar'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '2' reason for change: Data Entry Error	(b) (4)	
	Aastha KC (b) (4)	13 Nov 2020 20:12:10
	(b) (4)	
User entered '450'	Aastha KC (b) (4)	23 Oct 2020 14:56:03
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'mg (mg)'	Aastha KC (b) (4)	23 Oct 2020 14:56:03
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:56:03
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:56:03
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered '01 Oct 2017'	Aastha KC (b) (4)	23 Oct 2020 14:56:03
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 14:56:03
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 15:52:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:52:54
User entered 'No (N)' reason for change: Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 15:52:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 14:56:03
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:56:03
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 14:56:03

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: PALIPERIDONE PALMITATE, PRODUCTSYNONYM: INVEGA SUSTENNA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:59:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 14:59:31
Data point term sent to Coder	System	23 Oct 2020 14:58:38
User entered 'Invega Sustenna'	Aastha KC (b) (4)	23 Oct 2020 14:57:39

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'schizoaffective bipolar'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:57:39

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '234'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:57:39

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'every month (QM)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:57:39

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 Oct 2017'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 14:57:39

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:52:58
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:52:58
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:52:58
User entered empty.	(b) (4)	
	System	23 Oct 2020 14:57:39
	Aastha KC (b) (4)	23 Oct 2020 14:57:39
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 14:57:39

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 14:57:39

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	23 Oct 2020 14:57:39

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: OTHER ANTI-DEMENTIA DRUGS, PRODUCT: MEMANTINE HYDROCHLORIDE, PRODUCTSYNONYM: NAMENDA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 05:55:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 05:55:04
Data point term sent to Coder	System	23 Oct 2020 15:00:42
User entered 'Nemenda'	Aastha KC (b) (4)	23 Oct 2020 15:00:36

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Migraines'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:00:36

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '10'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'mg (mg)'	Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'twice daily (BID)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2018'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:00:36

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:00:36

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:53:06
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:53:06
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:53:06
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:00:36
	Aastha KC (b) (4)	23 Oct 2020 15:00:36
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Oct 2020 15:00:36

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:00:36

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:00:36

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
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: ACICLOVIR, PRODUCTS YNonym: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:04:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:04:32
Data point term sent to Coder	System	23 Oct 2020 15:03:49
User entered 'Acyclovir'	Aastha KC (b) (4)	23 Oct 2020 15:03:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Herpes simplex 2'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '400'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:03:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:03:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered '01 Jun 2018'	Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:03:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:53:10
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:53:10
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:53:10
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:03:35
	Aastha KC (b) (4)	23 Oct 2020 15:03:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:03:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:03:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:03:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE HYDROCHLORIDE, PRODUCTSYNONYM: ZANAFLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:09:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:09:34
Data point term sent to Coder	System	23 Oct 2020 15:09:00
User entered 'Zanaflex'	Aastha KC (b) (4)	23 Oct 2020 15:08:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Migraines, Back Spasms'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '4-8'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:08:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'as needed (PRN)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:08:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2005'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:08:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:54:11
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:54:11
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:54:11
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:08:26
	Aastha KC (b) (4)	23 Oct 2020 15:08:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:08:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:08:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:08:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:43:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:43:14
Data point term sent to Coder	System	29 Oct 2020 18:18:58
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	29 Oct 2020 18:18:25
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'Updated' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 18:18:25
User entered 'FLEXERIL (Cyclobenzaprine HCl)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:18:18
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	26 Oct 2020 13:11:21
Data point term sent to Coder	System	23 Oct 2020 15:15:13
Data point term sent to Coder	System	23 Oct 2020 15:14:11
User entered 'Flexeril'	Aastha KC (b) (4)	23 Oct 2020 15:13:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
Query 'Per DM CLR: Con Med start date of BACK SPASMS is prior to the start date of the corresponding MH condition (BACK SPASMS - 01 JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 05:34:42
User opened query 'Per DM CLR: Con Med start date of BACK SPASMS is prior to the start date of the corresponding MH condition (BACK SPASMS - 01 JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:34:24
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 15:14:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:14:38
User entered 'Back Spams, Back Pain' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:14:38
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 15:13:54
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:13:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '10'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:13:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'as needed (PRN)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:13:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Con Med start date of BACK SPASMS is prior to the start date of the corresponding MH condition (BACK SPASMS - 01 JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:23:59
Query 'Per DM CLR: Con Med start date of BACK SPASMS is prior to the start date of the corresponding MH condition (BACK SPASMS - 01 JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'Updated MH and Con Med' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 21:40:18
User opened query 'Per DM CLR: Con Med start date of BACK SPASMS is prior to the start date of the corresponding MH condition (BACK SPASMS - 01 JUN 2019). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:34:47
User entered '01 UNK 2013'	Aastha KC (b) (4)	23 Oct 2020 15:13:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:54:18
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:54:18
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:54:18
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:13:54
	Aastha KC (b) (4)	23 Oct 2020 15:13:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:13:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:13:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:13:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: ELETRIPTAN HYDROBROMIDE, PRODUCTSYNONYM: RELPAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:25:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 07:25:14
Data point term sent to Coder	System	23 Oct 2020 15:17:19
User entered 'REPLAX'	Aastha KC (b) (4)	23 Oct 2020 15:16:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Migraines'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '40'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 17:57:21
User entered 'mg (mg)' reason for change: Data Entry Error	System	23 Oct 2020 17:57:21
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 17:57:21
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:16:26
	Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:16:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'as needed (PRN)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:16:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'Oral (ORAL)'	Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered '01 UNK 2005'	Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:16:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 15:54:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:54:24
User entered 'No (N)' reason for change: Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 15:54:24
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 15:16:26
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:16:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:16:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:16:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:16:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 05:54:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 05:54:21
Data point term sent to Coder	System	23 Oct 2020 15:20:29
User entered 'Torodol'	Aastha KC (b) (4)	23 Oct 2020 15:19:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Migraines'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:19:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '30'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'mg (mg)'	Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'as needed (PRN)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:19:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2005'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:20:36
User entered 'Yes (Y)' reason for change: Data Entry Error	System	23 Oct 2020 15:20:36
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:20:36
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:19:35
	Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:54:30
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:54:30
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:54:30
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:19:35
	Aastha KC (b) (4)	23 Oct 2020 15:19:35
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:19:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:19:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:19:35

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: PHENOTHIAZINES WITH PIPERAZINE STRUCTURE, PRODUCT: PROCHLORPERAZINE EDISYLATE, PRODUCTSYNONYM: COMPAZINE [PROCHLORPERAZINE EDISYLATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:23:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:23:43
Data point term sent to Coder	System	23 Oct 2020 15:22:39
User entered 'Compazine'	Aastha KC (b) (4)	23 Oct 2020 15:22:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Migraines'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:22:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '10'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:22:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:22:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'as needed (PRN)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2005' reason for change:	(b) (4)	
Data Entry Error	Aastha KC (b) (4)	13 Nov 2020 20:16:57
User entered '01 UNK 2012'	(b) (4)	
	Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:54:35
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:54:35
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:54:35
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:22:09
	Aastha KC (b) (4)	23 Oct 2020 15:22:09
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:22:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:22:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:22:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: INDOMETACIN, PRODUCTSYNONYM: INDOMETHACIN [INDOMETACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:26:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:26:35
Data point term sent to Coder	System	23 Oct 2020 15:25:42
User entered 'indomethacin'	Aastha KC (b) (4)	23 Oct 2020 15:24:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Migraines'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '25'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:24:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'as needed (PRN)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2012'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:24:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:54:40
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:54:40
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:54:40
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:24:54
	Aastha KC (b) (4)	23 Oct 2020 15:24:54
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:24:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:24:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:24:54

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:28:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:28:39
Data point term sent to Coder	System	23 Oct 2020 15:27:48
User entered 'Albuterol'	Aastha KC (b) (4)	23 Oct 2020 15:26:57

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:26:57
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Mild Asthma'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:26:57

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '90'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:26:57
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:28:11
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:51:33
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 12:50:49
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:36:01
User entered 'mg (mg)'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:26:57

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:26:57
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'as needed (PRN)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:26:57
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:26:57
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:26:57

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:26:57
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2013'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:26:57
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:26:57

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:26:57
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:26:57

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:54:45
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 15:54:45
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:54:45
User entered empty.	(b) (4)	
	System	23 Oct 2020 15:26:57
	Aastha KC (b) (4)	23 Oct 2020 15:26:57
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:26:57

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:26:57

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:26:57

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:30:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:30:34
Data point term sent to Coder	System	23 Oct 2020 15:28:53
User entered 'magnesium'	Aastha KC (b) (4)	23 Oct 2020 15:28:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Migraines'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '400'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'mg (mg)'	Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:28:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2017'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:28:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:28:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:28:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:28:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:28:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 03:26:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 03:26:32
Data point term sent to Coder	System	23 Oct 2020 15:34:01
User entered 'Colace'	Aastha KC (b) (4)	23 Oct 2020 15:33:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Irritable bowel syndrome'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '250'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'twice daily (BID)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2017'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:33:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:33:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Oct 2020 15:33:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:33:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:33:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: BILE AND LIVER THERAPY, ATC: LIVER THERAPY, LIPOTROPICS, ATC: LIVER THERAPY, PRODUCT: SILYBUM MARIANUM, PRODUCTSYNONYM: MILK THISTLE [SILYBUM MARIANUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 12:52:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 12:52:50
Data point term sent to Coder	System	25 Jan 2021 12:52:25
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 12:51:55
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SILYBUM MARIANUM, PRODUCTSYNONYM: MILK THISTLE [SILYBUM MARIANUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 06:05:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 06:05:26
Data point term sent to Coder	System	23 Oct 2020 15:35:04
User entered 'Milk Thistle'	Aastha KC (b) (4)	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Jan 2021 12:51:55
User entered 'No (N)'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded. Else, If this was used as a preventive medication, update Prophylaxis field to YES. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:40:38
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded. Else, If this was used as a preventive medication, update Prophylaxis field to YES.	(b) (4), (b) (6)	25 Jan 2021 12:52:01
' answered with 'updated' (Site from DM).		
User entered 'GENERAL health' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 12:51:55
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded. Else, If this was used as a preventive medication, update Prophylaxis field to YES. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:36:58
User entered 'General'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '324'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:34:27
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:34:27
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:34:27
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:34:27
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:34:27
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2018'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:34:27
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 15:34:27
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:34:27
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:34:27

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 15:52:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 15:52:02
Data point term sent to Coder	System	18 Dec 2020 15:50:31
Coding entries removed.	(b) (4), (b) (6)	18 Dec 2020 15:50:30
User entered 'ZYRTEC' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 15:50:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:40:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:40:42
Data point term sent to Coder	System	23 Oct 2020 15:39:12
User entered 'Zertec'	Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Seasonal Allergies'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:38:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered '10'	Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'mg (mg)'	Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:38:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2018'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:38:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:38:26
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:38:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:38:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:38:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 23:32:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 23:32:31
Data point term sent to Coder	System	30 Nov 2020 15:28:11
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	30 Nov 2020 15:27:40
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'UPDATED' (Site from System).	Kelly Likos (b) (4)	30 Nov 2020 15:27:40
User entered 'RISTELA [L-ARGININE, L-CITRULLINE, ROSAVITA ROSE HIPS EXTRACT, PCYNOGENOL FRENCH MARITIME PINE BARK EXTRACT]' reason for change: Data Entry Error	Kelly Likos (b) (4)	30 Nov 2020 15:27:32
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 09:56:08
Data point term sent to Coder	System	23 Oct 2020 15:47:33

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Ristela'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:41:06
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:50:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 12:50:20
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:38:47
User entered 'No (N)'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Women Health's'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '2'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:46:48
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'tablet (TABLET)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:46:48
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:46:48
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:46:48
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered '01 Mar 2020'	Aastha KC (b) (4)	23 Oct 2020 15:46:48
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 15:46:48
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 15:46:48
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:46:48
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:46:48

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:49:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:49:35
Data point term sent to Coder	System	23 Oct 2020 15:48:35
User entered 'Probiotic'	Aastha KC (b) (4)	23 Oct 2020 15:48:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Irritable bowel syndrome'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:48:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'unknown'	Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 18:01:53
User entered 'Other (OTHER)' reason for change: Data Entry Error	System	23 Oct 2020 18:01:53
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 18:01:53
User entered empty; reason for change Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 15:48:50
Query 'Data is required. Please complete.' answered by data change (Site from System).		
User entered 'Other (OTHER)' reason for change: Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 15:48:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	23 Oct 2020 15:48:43
User closed query 'Data is required. Please complete.' (Site from System).		
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 15:48:43
User entered 'Other (OTHER)' reason for change: Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 15:48:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	23 Oct 2020 15:48:36
User closed query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:48:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	System	23 Oct 2020 15:48:25
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 15:48:25
User entered empty.	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	23 Oct 2020 18:02:06
User entered 'unknown' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	23 Oct 2020 18:02:06
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	23 Oct 2020 18:01:53
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	23 Oct 2020 15:48:50
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	23 Oct 2020 15:48:43
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	23 Oct 2020 15:48:36
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	23 Oct 2020 15:48:25
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:48:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:48:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered '01 May 2020'	Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered '0'	Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:48:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:48:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:48:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:48:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query ""Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 ""Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses"" (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:59:27
Query ""Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 ""Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses"" answered with 'As per PI, medication does not lead to participant discontinuation.' (Site from DM).	Isaac Perez (b) (4)	15 Feb 2021 20:19:01
User opened query ""Per MM, please confirm if this is prohibited medication per protocol section 6.4.3 ""Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses"" (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:04:00
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE, ATC: RETINOIDS FOR TREATMENT OF ACNE, PRODUCT: ISOTRETINOIN, PRODUCTSYNONYM: ACCUTANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 22:19:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 22:19:55
Data point term sent to Coder	System	25 Jan 2021 12:53:27
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 12:53:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids <u>> 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:29:22
Query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' answered with 'PI does not consider this an immunosuppressant/ immune modifying drug' (Site from DM).	Christina Bacher (b) (4) (b) (4)	20 Nov 2020 20:00:26
User opened query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 18:30:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE, ATC: RETINOIDS FOR TREATMENT OF ACNE, PRODUCT: ISOTRETINOIN, PRODUCTSYNONYM: ACCUTANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:39:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:39:41
Data point term sent to Coder	System	23 Oct 2020 15:58:55
User entered 'Accutane'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:58:12

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 15:58:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please write out medical abbreviations. Review and update Con Med eCRF as appropriate and ensure to reconcile with any corresponding MH entry, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:42:16
Query 'Per DM CLR: Please write out medical abbreviations. Review and update Con Med eCRF as appropriate and ensure to reconcile with any corresponding MH entry, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:53:17
User entered 'Hidradenitis Suppurativa' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 12:53:13
User opened query 'Per DM CLR: Please write out medical abbreviations. Review and update Con Med eCRF as appropriate and ensure to reconcile with any corresponding MH entry, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:39:41
User entered 'HDS'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:58:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '40'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:58:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:58:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:58:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:58:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:58:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:58:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:58:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 Aug 2020'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:58:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:58:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:58:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 15:58:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 15:58:12
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:58:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:58:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:58:12

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: PEROXIDES, PRODUCT: BENZOYL PEROXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 23:44:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 23:44:04
Data point term sent to Coder	System	25 Jan 2021 12:54:28
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 12:54:15
User entered 'BENZOYL PEROXIDE (5% Strength)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 12:54:15
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: PEROXIDES, PRODUCT: BENZOYL PEROXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:21:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:21:04
Data point term sent to Coder	System	13 Nov 2020 20:38:05
Coding entries removed.	Aastha KC (b) (4)	13 Nov 2020 20:37:27
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: PEROXIDES, PRODUCT: BENZOYL PEROXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 03:13:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 03:13:28
Data point term sent to Coder	System	23 Oct 2020 16:00:59
User entered 'Benzel Peroxide'	Aastha KC (b) (4)	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 16:00:45
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Hidradenitis suppurativa' reason for change: Data Entry Error	(b) (4)	
	Aastha KC (b) (4)	13 Nov 2020 20:37:27
	(b) (4)	
User entered 'Tonsillectomy'	Aastha KC (b) (4)	23 Oct 2020 16:00:45
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please note 5% appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., BENZEL PEROXIDE 5%) and list the specific dose and unit (e.g. Dose = 1; Other Unit, Specify = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:44:26
Query 'Per DM CLR: Please note 5% appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., BENZEL PEROXIDE 5%) and list the specific dose and unit (e.g. Dose = 1; Other Unit, Specify = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 12:55:10
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 12:54:15
User opened query 'Per DM CLR: Please note 5% appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., BENZEL PEROXIDE 5%) and list the specific dose and unit (e.g. Dose = 1; Other Unit, Specify = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:40:30
User entered '5'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Other (OTHER)'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Application' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Jan 2021 12:54:15
User entered '%'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 16:00:45
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 16:00:45
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Topical (TOPICAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 16:00:45
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 16:00:45
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2018'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 16:00:45
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 16:00:45
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 16:00:45

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 07:33:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 07:33:18
Data point term sent to Coder	System	25 Jan 2021 12:56:28
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 12:55:55
User entered 'CLINDAMYCIN 1%/30g' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 12:55:55
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: ANTIINFECTIVES FOR TREATMENT OF ACNE, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 20:43:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 20:43:43
Data point term sent to Coder	System	23 Oct 2020 17:53:21
User entered 'Clindamycin'	Aastha KC (b) (4)	23 Oct 2020 17:52:50
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 17:52:50
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'hidradenitis suppurativa'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please note, 1% appears to be a concentration/strength and 30g appears to be the whole content, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., CLINDAMYCIN 1%) and list the specific dose and unit (e.g. Dose = 1; Other Unit, Specify = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:45:08
Query 'Per DM CLR: Please note, 1% appears to be a concentration/strength and 30g appears to be the whole content, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., CLINDAMYCIN 1%) and list the specific dose and unit (e.g. Dose = 1; Other Unit, Specify = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:02:45
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 12:55:55
User opened query 'Per DM CLR: Please note, 1% appears to be a concentration/strength and 30g appears to be the whole content, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., CLINDAMYCIN 1%) and list the specific dose and unit (e.g. Dose = 1; Other Unit, Specify = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:41:09
User entered '1%/30' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:38:01
User entered '30'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 13:03:15
User entered 'Other (OTHER)' reason for change: Data Entry Error	System	25 Jan 2021 13:03:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 13:03:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 12:55:55
User entered 'g (g)'	System	25 Jan 2021 12:55:55
	(b) (4), (b) (6)	25 Jan 2021 12:55:55
	Aastha KC (b) (4)	23 Oct 2020 17:52:50
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'application' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Jan 2021 12:55:55
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:52:50
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Topical (TOPICAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:52:50
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:52:50
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2018'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:52:50
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 17:52:50
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 17:52:50

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 11:00:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 11:00:12
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	25 Jan 2021 13:04:30 25 Jan 2021 13:04:09
User entered 'NYSTATIN 1,000unit/gram' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 13:04:09
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 04:11:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 04:11:33
Data point term sent to Coder User entered 'Nystatin'	System Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:55:24 23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Hidradenitis Suppurativa'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please review Dose as this is not the standard dose of this medication. Review if dose availability should be recorded together with the medication name and update dose and dose unit with the number of applications administered (e.g. Dose = 1; Other Unit, Specify = Application) for this topical medication. Update accordingly or provide comment.' (Site from DM). Query 'Per DM CLR: Please review Dose as this is not the standard dose of this medication. Review if dose availability should be recorded together with the medication name and update dose and dose unit with the number of applications administered (e.g. Dose = 1; Other Unit, Specify = Application) for this topical medication. Update accordingly or provide comment.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:45:55
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 13:04:15
User opened query 'Per DM CLR: Please review Dose as this is not the standard dose of this medication. Review if dose availability should be recorded together with the medication name and update dose and dose unit with the number of applications administered (e.g. Dose = 1; Other Unit, Specify = Application) for this topical medication. Update accordingly or provide comment.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:04:09
User entered '1000'	Aastha KC (b) (4)	14 Jan 2021 05:42:14
	(b) (4)	23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Aastha KC (b) (4)	23 Oct 2020 17:54:54
User entered 'g (g)'	(b) (4)	
	Aastha KC (b) (4)	23 Oct 2020 17:54:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'application' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:04:09
User entered 'units/gram' reason for change: Data Entry Error	Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:54:54
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:54:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:54:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Topical (TOPICAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:54:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 17:54:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2018'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:54:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 17:54:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 17:54:30
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 17:54:30

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:10:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:10:40
User closed query 'Per DM CLR: Please review the drug strength recorded as this is not the standard drug strength for this medication. Please correct the drug strength in the medication name.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 18:30:47
Data point term sent to Coder	System	10 Mar 2021 20:32:40
Query 'Per DM CLR: Please review the drug strength recorded as this is not the standard drug strength for this medication. Please correct the drug strength in the medication name.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 20:32:40
Coding entries removed.	(b) (4), (b) (6)	10 Mar 2021 20:32:33
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 20:32:33
User entered 'TRIAMCINOLONE .1%/15G' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 20:32:33
User opened query 'Per DM CLR: Please review the drug strength recorded as this is not the standard drug strength for this medication. Please correct the drug strength in the medication name.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 00:04:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 13:23:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 13:23:47
Data point term sent to Coder	System	25 Jan 2021 13:05:31
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 13:05:31
User entered 'TRIAMCINOLONE .01%/15g' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 13:05:31
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:47:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:47:42
Data point term sent to Coder	System	18 Dec 2020 15:51:33
Coding entries removed.	(b) (4), (b) (6)	18 Dec 2020 15:51:32
User entered 'TRIAMCINOLONE' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 15:51:32
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 04:26:26

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Triamcinallne'	Coder Import (b) (4) (b) (4) System Aastha KC (b) (4) (b) (4)	24 Oct 2020 04:26:26 23 Oct 2020 17:56:25 23 Oct 2020 17:56:15

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 17:56:15
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Hidradenitis Suppurativa'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:56:15

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please note, 0.01% appears to be a concentration/strength and 15g appears to be the whole content, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., TRIAMCINALLNE 0.01%) and list the specific dose and unit (e.g. Dose = 1; Other Unit, Specify = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:46:29
Query 'Per DM CLR: Please note, 0.01% appears to be a concentration/strength and 15g appears to be the whole content, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., TRIAMCINALLNE 0.01%) and list the specific dose and unit (e.g. Dose = 1; Other Unit, Specify = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:05:39
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 13:05:31
User opened query 'Per DM CLR: Please note, 0.01% appears to be a concentration/strength and 15g appears to be the whole content, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., TRIAMCINALLNE 0.01%) and list the specific dose and unit (e.g. Dose = 1; Other Unit, Specify = Application) within the DOSE and UNIT fields. Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:43:27
User entered '.01%/15' reason for change: Data Entry Error	Aastha KC (b) (4)	13 Nov 2020 20:39:21
User entered '15'	Aastha KC (b) (4)	23 Oct 2020 17:56:15

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:05:31
User entered 'g (g)'	Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:56:15

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'application' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:05:31
User entered empty.	Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:56:15

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:56:15
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:56:15
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Topical (TOPICAL)'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:56:15
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:56:15
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2018'	(b) (4) Aastha KC (b) (4)	23 Oct 2020 17:56:15
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	23 Oct 2020 17:56:15

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered 'Yes (Y)'	Aastha KC (b) (4)	23 Oct 2020 17:56:15
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
	(b) (4)	
User entered empty.	Aastha KC (b) (4)	23 Oct 2020 17:56:15
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 17:56:53
User entered 'No (N)' reason for change: Data Entry Error	System	23 Oct 2020 17:56:53
User opened query 'Data is required. Please complete.' (Site from System).	Aastha KC (b) (4)	23 Oct 2020 17:56:53
User entered empty.	(b) (4)	
	System	23 Oct 2020 17:56:15
	Aastha KC (b) (4)	23 Oct 2020 17:56:15
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:56:15

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:56:15

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 17:56:15

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 15:44:24
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Nov 2020 15:44:24
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 15:43:33
User entered 'Aleve'	(b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Migraines'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '220'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Nov 2020 15:43:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 15:43:13
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:43:13
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:43:09
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2010'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:43:09

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIGRAINES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:47:04
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIGRAINES should be recorded, and update con med indication or provide clarification. ' answered with 'additional treatment, not worsening' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:06:59
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIGRAINES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:44:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:21:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 15:21:50
Data point term sent to Coder	System	12 Nov 2020 15:20:50
User entered 'Botox'	(b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Migraines'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'every 90 days'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:19:29
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 14:31:00
User entered 'UN UNK 2014' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 14:31:00
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '04 Nov 2020'	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:20:43

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 20:43:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 20:43:57
Data point term sent to Coder	System	13 Nov 2020 20:43:15
Data point term sent to Coder	System	13 Nov 2020 20:42:14
User entered 'Methylprednisolone'	Aastha KC (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 20:42:23
User entered 'Neck Pain' reason for change: Data Entry Error	Aastha KC (b) (4)	13 Nov 2020 20:42:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	13 Nov 2020 20:42:07
	Aastha KC (b) (4)	13 Nov 2020 20:42:07
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Unkown'	(b) (4) Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Other (OTHER)'	Aastha KC (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Unknown'	Aastha KC (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	Aastha KC (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	Aastha KC (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '5 Nov 2020'	Aastha KC (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '12 Nov 2020'	(b) (4) Aastha KC (b) (4) (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Aastha KC (b) (4)	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User entered '1'	System	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User entered '1'	System	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:22
User entered '804 (804)'	System	13 Nov 2020 20:42:07

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening FACIAL ACNE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:47:59
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening FACIAL ACNE should be recorded, and update con med indication or provide clarification. ' answered with 'not worsening' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:07:17
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening FACIAL ACNE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:45:23
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 04:00:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 04:00:59
Data point term sent to Coder	System	19 Nov 2020 22:04:07
User entered 'Hydrocortisone Creme 2.5 %'	Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Facial Acne'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '1'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Other (OTHER)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Thin layer on face'	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:03:22
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:03:22
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Topical (TOPICAL)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '19 Nov 2020'	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:03:22
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:03:22

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: PEARL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Nov 2020 03:34:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:34:53
Data point term sent to Coder	System	19 Nov 2020 22:05:08
User entered 'Pearl Creme'	Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Facial Acne'	(b) (4) Bezuayehu Mandefro (b) (4) (b) (4)	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '1'	(b) (4) Bezuayehu Mandefro (b) (4) (b) (4)	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Other (OTHER)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'light layer on face'	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:04:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Topical (TOPICAL)'	(b) (4) Bezuayehu Mandefro (b) (4) (b) (4)	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:04:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 Aug 2020'	(b) (4) Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:04:16
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Bezuayehu Mandefro (b) (4) (b) (4)	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:04:16

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE, PRODUCTSYNONYM: TRUVADA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 22:06:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 22:06:49
Data point term sent to Coder	System	19 Nov 2020 22:06:09
User entered 'Truvada'	Bezuayehu Mandefro (b) (4)	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Prevent HIV infection'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '200-300'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:06:00
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once daily (QD)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:06:00
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	(b) (4) Bezuayehu Mandefro (b) (4) (b) (4)	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:06:00
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '01 UNK 2019'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Bezuayehu Mandefro	19 Nov 2020 22:06:00
	(b) (4)	

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Bezuayehu Mandefro (b) (4) [REDACTED] [REDACTED]	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:06:00

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CODEINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 15:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Dec 2020 15:54:42
Data point term sent to Coder	System	18 Dec 2020 15:52:34
Coding entries removed.	(b) (4), (b) (6)	18 Dec 2020 15:52:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CODEINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Dec 2020 23:49:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Dec 2020 23:49:55
Data point term sent to Coder	System	10 Dec 2020 22:09:30
User entered 'Codeine'	Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Symptomatic covid 19' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 15:52:23
User entered 'illness visit symptoms- cough'	Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'UNK'	Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Other (OTHER)'	Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'UNK'	Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once (ONCE)'	(b) (4) Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Oral (ORAL)'	Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '9 Dec 2020'	Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4) Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	10 Dec 2020 22:09:29
User entered '9 Dec 2020' reason for change: New Information	Christina Bacher (b) (4)	10 Dec 2020 22:09:29
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	10 Dec 2020 22:08:31
User entered empty.	Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	Christina Bacher (b) (4)	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User entered empty.	System	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User entered empty.	System	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:26
User entered empty.	System	10 Dec 2020 22:08:31

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 15:02:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	25 Jan 2021 15:02:47
Data point term sent to Coder Coding entries removed.	System	25 Jan 2021 15:02:45
	(b) (4), (b) (6)	25 Jan 2021 15:01:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Dec 2020 21:35:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	12 Dec 2020 21:35:04
Data point term sent to Coder	System	12 Dec 2020 21:33:58
User entered 'Aleve (Naproxen)'	(b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 05:49:07
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'corrected, taken mor migraines listed in med history' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 15:02:10
User entered 'Migraines' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 15:01:59
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:42:52
User entered 'headache'	(b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '220'	(b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Dec 2020 21:33:20
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Dec 2020 21:33:20
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Dec 2020 21:33:13
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '0'	(b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	12 Dec 2020 21:33:26
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Dec 2020 21:33:26
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Dec 2020 21:33:13
User entered empty.	(b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User entered empty.	System	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User entered empty.	System	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:59:28
User entered empty.	System	12 Dec 2020 21:33:13

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: FREMANEZUMAB, PRODUCTSYNONYM: AJOVY [FREMANEZUMAB] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 15:54:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 15:54:21
Data point term sent to Coder	System	06 Apr 2021 15:52:53
User entered 'Ajoyv'	(b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered 'migraines'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered '225'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered 'every month (QM)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:38:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	06 Apr 2021 15:52:34

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per MM: please confirm if this is prohibited medication per protocol section 6.4.3 "Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses" ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 16:48:26
Query 'Per MM: please confirm if this is prohibited medication per protocol section 6.4.3 "Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses" ' answered with 'not exclusionary per PI, not immunosuppressive' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:40:31
User opened query 'Per MM: please confirm if this is prohibited medication per protocol section 6.4.3 "Concomitant Medications and Vaccines that May Lead to the Elimination of a Participant from Per-Protocol Analyses" ' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 19:53:30
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE, ATC: RETINOIDS FOR TREATMENT OF ACNE, PRODUCT: ISOTRETINOIN, PRODUCTSYNONYM: ACCUTANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:01:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:01:35
Data point term sent to Coder	System	19 Apr 2021 13:01:05
User entered 'Accutane'	(b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'Facial Acne'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered '40'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:44:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 11 Aug 2021 22:55:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 13:00:37

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:55:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:30
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 18:03:48
User entered 'No (N)'	Aastha KC (b) (4)	23 Oct 2020 18:02:28

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:55:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:04:49

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:55:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Intrauterine Device insertion'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:04:49

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:04:49

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:55:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Participant had Mirena intrauterine device insertion.'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:04:49

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:55:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:05

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:55:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Cervical Spine X-ray'	(b) (4), (b) (6)	12 Nov 2020 18:08:05

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:53:59
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'A cervical spine x-ray was performed relating to the two small bilateral pleural effusions. This is indicated in the narrative of the AE - Two Small Bilateral Pleural Effusions.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 14:26:37
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:41:42
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Nov 2020 18:08:05

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:55:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:05

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Aug 2021 22:55:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '29 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 18:08:19

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Aug 2021 22:55:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Thoracic Spine X-ray'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:19

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:54:11
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'A cervical spine x-ray was performed relating to the two small bilateral pleural effusions. This is indicated in the narrative of the AE - Two Small Bilateral Pleural Effusions.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 14:26:42
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:41:50
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	12 Nov 2020 18:08:19

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Aug 2021 22:55:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:19

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Aug 2021 22:55:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:08
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:31

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Aug 2021 22:55:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:08
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Chest X-ray'	(b) (4), (b) (6)	12 Nov 2020 18:08:31

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:08
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:31

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Aug 2021 22:55:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:08
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:31

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Aug 2021 22:55:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:11
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '25 Nov 2020'	Christina Bacher (b) (4)	25 Nov 2020 14:44:18

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Aug 2021 22:55:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:11
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered 'Thoracentesis'	Christina Bacher (b) (4)	25 Nov 2020 14:44:18

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Aug 2021 22:55:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:11
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	30 Nov 2020 15:23:18
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	25 Nov 2020 14:44:18
User entered 'Adverse Event (AE)'	Christina Bacher (b) (4) (b) (4)	25 Nov 2020 14:44:18

US3632154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Aug 2021 22:55:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:11
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered empty; reason for change Data Entry Error	Kelly Likos (b) (4)	30 Nov 2020 15:23:18
User entered 'Participant is having thoracentesis for the AE of bilateral effusions.'	Christina Bacher (b) (4)	25 Nov 2020 14:44:18

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered		
'USA-US120-2020-MRNA-1273-P301000011'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'Colleen'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'Kelley'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'GA'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'US'	System	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '3'	(b) (4)	26 Jan 2021 16:24:24
User entered '2'	System	07 Jan 2021 20:44:37
User entered '1'	System	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered		
'USA-US120-2020-MRNA-1273-P301000011'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'Colleen'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'Kelley'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'GA'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'US'	System	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '3'	(b) (4)	26 Jan 2021 16:24:24
User entered '2'	System	07 Jan 2021 20:44:37
User entered '1'	System	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:55:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:33:03
User entered '16/Dec/2020 10:36'	System	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:55:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:36:14
User entered 'I'	(b) (4), (b) (6)	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered		
'USA-US120-2020-MRNA-1273-P301000011'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'Colleen'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'Kelley'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'GA'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'US'	System	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '3'	(b) (4)	26 Jan 2021 16:24:24
User entered '2'	System	07 Jan 2021 20:44:37
User entered '1'	System	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:55:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:33:03
User entered '07/Jan/2021 20:44'	System	07 Jan 2021 20:44:37

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:55:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 16:24:31
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 20:44:37

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered		
'USA-US120-2020-MRNA-1273-P301000011'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'No (N)'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'Colleen'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'Kelley'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'GA'	System	16 Dec 2020 15:35:49

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:44:23
User entered 'US'	System	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:55:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
User entered '3'	(b) (4)	26 Jan 2021 16:24:24
User entered '2'	System	07 Jan 2021 20:44:37
User entered '1'	System	16 Dec 2020 15:36:08

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:55:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:33:03
User entered '26/Jan/2021 11:24'	System	26 Jan 2021 16:24:24

US3632154

Folder: SAE USA-US120-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:55:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:58:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:33:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 16:24:31
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 16:24:24